

AFFIRMATION V O T E

RESPONSE SHEET

TO: Annette Vietti-Cook
Secretary of the Commission

FROM: CHAIRMAN MESERVE

SUBJECT: SECY-01-0127 - DRAFT FINAL RULE: 10 CFR PART 63,
"DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN A
PROPOSED GEOLOGIC REPOSITORY AT YUCCA
MOUNTAIN NEVADA

Approved X with comment Disapproved Abstain

Not Participating Request Discussion

COMMENTS:

See attached comments.



SIGNATURE

August 10, 2001

DATE

Entered on "STARS" Yes No

COMMENTS OF CHAIRMAN MESERVE ON SECY-01-0127

SECY-01-0127 presents the draft final rule that would establish licensing criteria for a proposed geologic repository at Yucca Mountain, Nevada. The paper reflects a very significant effort for which the staff should be commended.

The Energy Policy Act of 1992 requires that NRC establish technical requirements and criteria that are consistent with standards for Yucca Mountain that are promulgated by EPA. Pub. L. No. 102-486, § 801, 106 Stat. 2921 (1992). EPA has recently promulgated its standards. 66 Fed. Reg. 32,073 (June 13, 2001). As a result, the draft final rule before us modifies NRC's proposed rule not only to respond to public comments, but also to implement the EPA standards.

The final EPA standards depart significantly from the NRC proposed rule by including a 15 mrem/yr individual protection standard and a 4 mrem/yr ground-water protection standard using EPA's maximum contaminant levels (MCLs). 40 C.F.R. §§ 197.20, 197.30. I am of the view that the 25 mrem/yr dose limit published in NRC's proposed rule is fully protective of public health and safety. I also am convinced that a separate standard to protect ground water is unnecessary and imposes needless burdens on the Department of Energy (DOE) that do not have a commensurate health and safety benefit. Moreover, I continue to be troubled by the use of outdated dosimetry by EPA in defining the MCLs for ground-water protection; the MCLs lack scientific foundation and have the unfortunate consequence of establishing differences in protection on a radionuclide-by-radionuclide basis.

Nonetheless, we are bound by law to implement the EPA standards. Accordingly, the staff has appropriately modified the NRC proposed rule to implement the EPA standards fully and thoughtfully. Subject to the comments noted below, I approve publication of the final rule in the Federal Register. In addition, I certify that the final rule does not have a significant financial impact on a substantial number of small entities.

1. The final rule and Statement of Considerations (SOC) should be revised to use "total effective dose equivalent" (TEDE) instead of "annual committed effective dose equivalent" (annual CEDE) for radiological doses to members of the public in the general environment and to the reasonably maximally exposed individual (RMEI). Although the final EPA standards employ the term "annual committed effective dose equivalent" (40 C.F.R. §§ 197.2, 197.20), TEDE and annual CEDE in this application are the same.¹ I favor the use of

¹ There are differences between TEDE and annual CEDE in some contexts. Specifically, in determining the external dose component of TEDE, our rule specifies use of the deep-dose equivalent. See 10 C.F.R. § 20.1003. The deep-dose equivalent is a point measurement that does not sum the doses to the organs or tissue through use of weighting factors. See 10 C.F.R. § 20.1201(c). This approach may reflect the fact that compliance with Part 20 is customarily assessed using a Thermo-Luminescent Device (TLD) or a film badge, and

TEDE in Part 63 because this is the standard NRC terminology. The needless proliferation of terminology for equivalent concepts should be avoided. The SOC should be modified to reflect this change and more thoroughly explain that TEDE is equivalent to annual CEDE in application to Yucca Mountain. Of course, in applying TEDE to members of the public in the general environment and to the RMEI, staff should provide for the use of effective dose equivalent, as opposed to deep-dose equivalent, when considering external exposures (as allowed under 10 C.F.R. § 20.1003).

As a separate matter, the differences in approach and terminology revealed by this issue and the recent confusion surrounding the assessment of external dose by some licensees (SECY-01-0140) demonstrate the need for staff to address when it is appropriate to use effective dose equivalent rather than deep-dose equivalent for assessing the dose from external sources of radioactivity.

2. The EPA standard defines the RMEI as a rural-residential exposed through the same general pathways as a subsistence farmer. 66 Fed. Reg. 32,092 (June 13, 2001). In describing the RMEI in the SOC for Part 63, staff indicates that the RMEI is a member of a farming community (SECY-01-0127, Attachment 2, at 84). Because the terminology is different, some might perceive a conflict between the EPA standards and Part 63. The staff should ensure that the appearance of a conflict is avoided in preparing the final *Federal Register* notice.

the results of such measurements reflect deep-dose equivalent. By contrast, in determining annual CEDE, the external dose component is determined using the effective dose equivalent, which involves summing the products of organ doses and weighting factors. See 40 C.F.R. § 197.2. In those situations in which the two measures of external dose differ, the effective dose equivalent approach probably provides a better estimate for measuring radiation risk.

In the context of compliance with the individual protection standard at Yucca Mountain, the external dose would clearly be very small in comparison to the committed dose. (The principal pathway of exposure is ingestion, which would result in internal exposure.) Moreover, Part 20 does allow for consideration of weighting factors for individual organs in the case of external exposures on a case-by-case basis. See 10 C.F.R. § 20.1003, Footnote 2 to Table on Organ Dose Weighting Factors. As a result, in assessing compliance with the individual protection standard, the staff intends to use effective dose equivalent for assessing external exposure. The computer codes used by NRC in decommissioning and HLW disposal currently calculate external doses using effective dose equivalent and not deep-dose equivalent. See NUREG/CR 6676, "Probabilistic Dose Analysis Using Parameter Distributions Developed for RESRAD and RESRAD-Build Codes," 3-1 (July 2000); NUREG-1464, "NRC Iterative Performance Assessment," 7-5 (October 1995); and NUREG/CR-5512, "Residual Contamination from Decommissioning, User's Manual DandD Version 2.1," Vol. 2, E-1 (April 2001). Consequently, the application of TEDE (using organ weighting factors for external doses) in assessing compliance with dose limits for members of the public in the general environment and the individual protection standard in connection with a geologic repository will yield exactly the same result as applying annual CEDE. See SECY-01-0127, Attachment 2, at 12.

3. The staff uses the term "soluble radionuclides" in the context of the human intrusion scenario. See § 63.322. Without further clarification, the term might invite debate as to what radionuclides should be considered as soluble. The staff should provide clarification as to the intended meaning of this term.

4. EPA's standard has three separate components -- the individual protection standard, the ground-water standards, and the human intrusion standard. In the draft final Part 63, the staff has indicated that only the individual protection and ground-water protection standards are severable. See § 63.343. In preparing the final *Federal Register* notice, the staff should work with EPA to ensure that the severability requirement is consistent with the EPA standard.

5. In § 63.322, the staff uses the term "unlikely natural processes and events," but provides no probability cutoffs for defining these events. This omission could result in uncertainty as to what natural processes and events should be considered. Consequently, following issuance of the final Part 63, staff should initiate an expedited rulemaking to establish the annual probability of occurrence that is seen to constitute an unlikely event or process.

6. The definition of high-level radioactive waste in § 63.202 is not appropriate for inclusion in the NRC rule (although it is appropriate in the EPA rule), because it would suggest incorrectly that the NRC intends to leave to another rulemaking the determination of whether irradiated reactor fuel should be deemed HLW.² A more appropriate approach is to adopt subpart (A) of the definition from the Nuclear Waste Policy Act of 1982 (42 U.S.C. § 10101(12)), as amended, as item (1) of the regulatory definition; add "irradiated reactor fuel" as item (2) of the definition; and to retain subpart (B) of the statutory definition as item (3) of the regulatory definition. Moreover, the definition of the term "high-level waste" in § 63.2 should be conformed to that in § 63.202.

7. The term "ground water" is defined in one part of the regulations to include the vadose zone (§ 63.2) and in another part to exclude that zone (§ 63.302). This will create needless confusion in the implementation of the rule. The staff should develop one definition that applies in all cases, but maintains consistency with the EPA standard.

8. Section 63.16(d) provides that the Director of NMSS "shall invite public comment on any comments that the Director makes to DOE on review of the DOE semiannual reports or on any other comments that the Director makes to DOE on site characterization and performance assessment." It is unclear whether this requirement is intended to apply to comments that the NRC might make concerning its review of DOE's Yucca Mountain Science and Engineering Report (YMS&ER) and related documents. However, I note that the staff has not proposed the solicitation of public comments in its schedule for completing its review of the YMS&ER and, if public comment were required, a substantial change in schedule could be required.

² As currently drafted, high-level radioactive waste is defined in § 63.202 to encompass highly radioactive material from reprocessing and "[o]ther highly radioactive material that the Commission, consistent with existing law, determines by rule requires permanent isolation." This section does not mention spent fuel.

Through Commission meetings with stakeholders on DOE's Viability Assessment and Draft Environmental Impact Statement, as well as from Advisory Committee on Nuclear Waste and NRC staff meetings with stakeholders on various technical issues, the Commission is aware of stakeholder concerns regarding the sufficiency of DOE's site characterization of Yucca Mountain. As a result, it is my view that additional input from stakeholders is unnecessary at this juncture. Although some stakeholders may want to provide direct input on the NRC's preliminary sufficiency comments, I believe that the Commission is in a position to make an informed decision without further stakeholder input. Moreover, although DOE's schedule for receiving comments has slipped, DOE has also delayed submitting documents supporting the YMS&ER to the staff. Consequently, it is unlikely that sufficient time will be available to provide for an extensive public involvement in NRC's preliminary site sufficiency comments. Therefore, the provision should be altered to make clear that the NRC comments on the YMS&ER will not themselves be subject to public comment.

9. I suggest a variety of edits to the draft *Federal Register* notice. These are reflected on the attached pages.

Valley, Las Vegas, and Caliente, Nevada, on June 15, 16, and 17, respectively. In developing this final rule, NRC considered comments received at these meetings along with written comments sent to NRC. The NRC also held a facilitated round table discussion on defense in depth as applied to a possible repository at Yucca Mountain on November 2, 1999, in Las Vegas.

The EPA published final radiation protection standards for the potential Yucca Mountain repository (40 CFR Part 197) on June 13, 2001 (66 FR 32073). The EPA standards differ ~~somewhat~~ from the performance objectives proposed by the Commission at 10 CFR Part 63.

EPA established an annual individual protection dose limit of 0.15 mSv (15 mrem), and EPA included separate ground-water protection criteria in its final standards. *for the purpose of protecting groundwater* In formal comments on EPA's proposed standards, dated November 3, 1999, the NRC staff supported a somewhat different approach. The NRC approach, which the Commission believes is adequately protective of public health and safety and groundwater, used a comprehensive, all-pathway limit. However, the ultimate decision was EPA's to make and, as called for under the EnPA, the Commission will change its technical requirements and criteria to be consistent with EPA's final standards.

II. Implementation of the Environmental Protection Agency Final Standards

The U.S. Environmental Protection Agency (EPA) published Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada, at 40 CFR Part 197 on June 13, 2001 (66 FR 32073). The Energy Policy Act of 1992, Pub. L. 102-486 (EnPA) directs the Commission to modify its technical requirements and criteria to be consistent with these standards. The Commission has imported the EPA standards into its final

However, the EPA standards do not specify a frequency for unlikely features, events, and processes, and acknowledges a value is to be specified by NRC (66 FR 32135). NRC fully supports excluding unlikely features, events, and processes from analyses for estimating compliance with the standards for human intrusion and ground-water protection. ^{Although} While we have provided no specific quantitative value for determining when exclusion of unlikely features, events, and processes is appropriate, the final regulations allow DOE to exclude unlikely features, events, and processes from the specified analyses with the prior approval of the Commission. The Commission recognizes that specification of a probability limit for unlikely features, events, and processes, as is done for "very" unlikely features, events, and processes, would be a more direct approach. Although the Commission considers a frequency for unlikely features, events, and processes would fall somewhere between 10^{-8} to 10^{-4} per year, the Commission has decided not to specify a value in the regulations at this time. The Commission considers this approach to be consistent with the intent of EPA's final standards and may revisit the question of specifying a numerical value by rulemaking in the future.

TOTAL EFFECTIVE DOSE EQUIVALENT

The EPA standards use the term "annual committed effective dose equivalent" (annual CEDE) to denote the total dose resulting from internal and external exposure to radiation resulting from a single year's exposure. A distinction is made between internal and external doses, because internal exposures (e.g., ingestion and inhalation of radionuclides) continue as long as the radioactive material remains within the body, and disproportionately affect internal organs, depending on where a particular radionuclide is retained in the body. Thus, internal exposure is determined by calculating a CEDE that takes into account the fact that internally

necessary, to conform to the new, site-specific standards to be developed by EPA. These same commenters noted that certain portions of proposed Part 63 depart significantly from Part 60 (e.g., there are no quantitative subsystem requirements) and, in the view of several commenters, weaken the safety requirements for any proposed repository at Yucca Mountain.

Response. The Commission is establishing a new, separate part of its regulations (at Part 63) that would apply only to the proposed repository at Yucca Mountain. The Commission will leave existing, generic regulations at Part 60 in place, modified only to state that they do not apply, nor may they be the subject of litigation, in any NRC licensing proceeding for a repository at Yucca Mountain. The Commission believes this to be the most direct and ~~time~~-efficient approach for specifying concise, site specific criteria for Yucca Mountain that are consistent with current assumptions, with site-specific information and performance assessment experience, and with EPA standards that apply solely to Yucca Mountain. ✓

In developing these criteria, the Commission sought to establish a coherent body of risk-informed, performance-based criteria for Yucca Mountain that is compatible with the Commission's overall philosophy of risk-informed, performance-based regulation ("Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities - Final Policy Statement"; 60 FR 42622; August 16, 1995). Stated succinctly, risk-informed, performance-based regulation is an approach in which risk insights, engineering analysis and judgment (e.g., defense in depth), and performance history are used to (1) focus attention on the most important activities, (2) establish objective criteria for evaluating performance, (3) develop measurable or calculable parameters for monitoring system and licensee performance, (4) provide flexibility to determine how to meet the established performance criteria in a way that will encourage and reward improved outcomes, and (5) focus on the results as the primary basis for regulatory decision making. The Commission believes that creating a new part of its regulations

approximately 20 km for Yucca Mountain). Generally, commenters asked NRC to set standards similar to, or more stringent than, those for WIPP. Some argued that a greater level of protection for people near Yucca Mountain was needed to offset potential exposures from other sources in the region (i.e., the Beatty low-level waste site and the Nevada Test Site, NTS).

Response. Final EPA standards adopted numerical limits that are comparable to those applied at WIPP. ~~In setting these limits, EPA took into consideration potential doses to the RMEI from other sources in the region.~~ Consistent with the views expressed by a majority of commenters, the Commission has awaited EPA's publication of final standards for Yucca Mountain, and is adopting final Part 63 criteria that are consistent with those limits, as required by law.

1.3 Multi-Staged Licensing

Issue 1: Should DOE be allowed to begin to place waste in the repository or to store waste in surface facilities once NRC has determined that there is enough space for initial operations, or should DOE have to wait until site construction is complete?

Comment. Many commenters indicated that NRC should not allow DOE to place waste in the repository until construction is complete. These commenters had general concerns that only after construction is completed would emergency equipment and safety precautions be available in case of an accident; and that any waste, if emplaced before completing construction, may pose an unnecessary risk to the construction workers. Alternatively, other commenters suggested that storage of waste at the repository should be allowed during construction as long as it does not pose any additional health or safety risk. The Nuclear Energy Institute (NEI) suggested that Part 63 should be changed so that NRC could authorize DOE to construct all or

The general requirements at § 63.131(a) explicitly link the performance confirmation program to DOE's performance assessment, albeit in terms of the barriers designed or assumed to function after permanent closure. ^{Although} ~~While~~ the primary focus of the performance confirmation program is on post-closure performance of the repository, and the NRC recognizes DOE's desire to focus on verifying the performance assessment (e.g., post-closure performance), it is important that the general requirements also include consideration of operational aspects of repository performance, for example, the ability to retrieve waste as required at § 63.111(e). An organized program of collecting subsurface information during repository construction and operation that confirms the design assumptions regarding the ability to retrieve waste is therefore an important performance confirmation activity. The NRC believes that the general requirements at § 63.131(a) allow DOE the flexibility to develop and implement an effective performance confirmation program focused on confirming assumed subsurface conditions, and assumed functionality of geologic and engineered systems and components, important to post-closure performance (i.e., performance of barriers important to isolation) and/or pre-closure repository operations (e.g., retrievability). In the proposed rule, the definition of performance confirmation in § 63.2 and the discussion of performance confirmation in § 63.102(m) do not clearly reflect the intent of § 63.131(a) and have been revised accordingly in the final rule. To adopt the changes to §§ 63.131(a) and 63.132(a) requested by DOE would remove consideration of operational aspects of repository performance from the performance confirmation program. For the reasons state above, the Commission does not agree that these changes are appropriate and has not adopted them.

Issue 2: Are the requirements for the performance confirmation program too prescriptive?

repository. The Commission believes that it is DOE's responsibility to specify the important geotechnical and design parameters to be evaluated through observation and measurement during construction and operation, subject to NRC approval through review and evaluation of the license application. DOE will provide this information in their performance confirmation plan included in the license application. If necessary, the NRC staff will provide guidance to DOE in this area through pre-licensing interactions and/or the YMRP. Section 63.132(c) has been revised to reflect these considerations.

Section 63.133 (Design testing) provides requirements for in-situ testing of seals and backfill and the thermal interaction effects of waste packages, backfill, rock, and ground water. DOE's recommendation that § 63.133 be revised so as to not limit testing to in-situ testing only is reasonable. Section 63.133(a) has been revised accordingly. The NRC has also revised § 63.133(a) to generally reference "engineered systems and components," with examples, so as to not limit tests to specific features that may or may not be included in the final design of the repository. Finally, the Commission has revised § 63.133(c) to require specific testing of the effectiveness of backfill placement and compaction only if backfill is included in the repository design.

Section 63.134 (Monitoring and testing waste packages) provides specific requirements for monitoring and testing waste packages consistent with the objectives of the performance confirmation program established at § 63.131(a). Waste packages are important engineered components designed to operate as barriers after permanent closure. Because the assumed long-term performance of waste package materials is based on short-term experimental data, monitoring waste package performance and related laboratory experiments are appropriate performance confirmation activities. ^{Although} While the NRC recognizes the need for reasonable cost constraints, it is important to note that it is DOE's responsibility to develop the details of a

3.1 Post-closure Safety Assessment

Issue 1: Can performance assessments be relied on as the sole quantitative technique for evaluating compliance with post-closure safety requirements?

Comment. DOE and NEI supported the risk-informed, performance-based approach. Additionally, NEI supported requirements in proposed Part 63 intended to ensure that DOE conducts and documents a high-quality performance assessment [e.g., features, events, and processes (FEPs) be described; relevant conceptual models be considered] and NEI also expressed a need for the NRC to effectively and clearly articulate this approach in future regulatory efforts. However, other commenters indicated that, although performance assessment is a highly informative methodology, its capability to model complex, coupled geologic systems over extended time periods has yet to be demonstrated. Confidence in performance assessments could be improved through testing on actual geologic systems and conducting suitable, long-term studies.

Response. Although repository post-closure performance is evaluated with respect to a single performance measure, ^{for individual protection} the NRC considers a broad range of information in arriving at a licensing decision. In the case of the proposed repository at Yucca Mountain, Part 63 contains a number of requirements (e.g., qualitative requirements for data and other information, the consideration and treatment of uncertainties, the demonstration of multiple barriers, performance confirmation program, and QA program) designed to increase confidence that the post-closure performance objective ^{is} satisfied. The Commission will rely on the performance assessment as well as DOE's compliance with these other requirements in making a decision, if DOE submits a license application for disposal of HLW at Yucca Mountain. The Commission believes the approach for performance assessment in the proposed rule is appropriate and is retained in the

63 not only requires DOE to account for uncertainty in its performance assessment but also contains a number of other requirements (e.g., use of multiple barriers, performance confirmation program) to compensate for residual uncertainties in estimating performance. The Commission will consider all these requirements in determining whether it has sufficient confidence (i.e., reasonable expectation) that DOE has demonstrated or has not demonstrated the safety of the repository. Specification of an acceptable level of uncertainty is neither practical nor appropriate due to the limited knowledge currently available to support any such specification and the range of uncertainties that would need to be addressed. The Commission believes the approach for performance assessment in the proposed rule, which includes the treatment of uncertainty, is appropriate and has retained this approach in the final rule.

The previous response, under Issue 1, discussed the requirements for the performance assessment. Many of these requirements, as discussed above, address uncertainty in the performance assessment. Some of these uncertainties will be directly included in the DOE's estimate of performance. For example, DOE is expected to conduct uncertainty analyses (i.e., evaluation of how uncertainty in parameter values affects uncertainty in the estimate of dose), including the consideration of disruptive events and associated probability of occurrence. Other uncertainties are not necessarily quantified but are considered during the development of the conceptual models for the performance assessment (e.g., consideration of alternative models, inclusion and exclusion of FEPs). If NRC were to specify an acceptable level of uncertainty, the specified value would be somewhat arbitrary because: (1) understanding of the site is evolving as site studies continue; (2) repository design options are still being evaluated; and (3) differences in the types of uncertainties (e.g., variability in measured parameters, modeling assumptions, expert judgment, etc.) complicate the specification. *The approach defined in* Part 63, which requires DOE to fully address uncertainties in its performance assessment rather than requiring DOE to meet a specific level of

uncertainty, is ~~considered an appropriate approach~~. The treatment of uncertainty in DOE's performance assessment will be an important part of NRC's review.

Regardless of the uncertainty in the performance assessment, Part 63 contains additional provisions to increase confidence that the post-closure performance objectives will be met. These provisions include requirements for multiple barriers, a performance confirmation program, and implementation of a QA program (see discussion under Issue 1). However, it should be kept in mind that the performance assessment evaluates "potential" doses, not "actual" doses. For example, Part 63 requires the performance assessment to assume for the next 10,000 years that the reasonably maximally exposed individual (RMEI) is a member of a community that: (1) exists where it will intercept potential releases from the repository and (2) uses ground water but never tests the quality of this water nor treats the ground water to remove any contaminants. This specification is considered appropriately conservative for evaluating performance but most likely is not an "accurate" prediction of what will happen during the next 10,000 years (see discussion under RMEI Characteristics and Reference Biosphere for more information on the RMEI). Although the Commission does not require an "accurate" prediction of the future, uncertainty in performance estimates cannot be so large that the Commission cannot find a reasonable expectation that the post-closure performance objectives will be met (see discussion under Reasonable Expectation). At this time, the Commission is not aware of any information that suggests the uncertainties are so large that NRC will be unable to make a regulatory decision regarding the safety of a potential repository at Yucca Mountain.

Issue 3: Do known conditions at the Yucca Mountain site and/or the potential for other adverse conditions make Yucca Mountain an unacceptable location for an HLW repository?

where and how an individual would be exposed, and (2) the dose limit should reflect impacts from either future energy development or past releases on the local community, such as ground-water releases from the NTS or the Beatty Low-Level Waste facility, in developing the standard.

Response. The purpose of the post-closure dose limit and the performance assessment is to ensure that future generations will be adequately protected. EPA has established, and the Commission ^{has} ~~will~~ incorporate^d, a dose limit of 0.15 mSv/year (15 mrem/year). The Commission is confident that this limit is fully protective and that it provides an added margin of safety beyond what is necessary to ensure public health and safety. The Commission has long held that a dose limit of 0.25 mSv/year (25 mrem/year) is (1) a reasonable and appropriate level of protection for future generations, (2) within the range of dose limits used for current sources of public exposure, and (3) accounts for the possibility of dose from other sources.

In judging the adequacy of a dose limit for waste management and other related activities, NRC considers recommendations from the International Commission on Radiological Protection (ICRP), National Council on Radiation Protection and Measurements (NCRP), EPA, and International Atomic Energy Agency (IAEA). The ICRP's and NCRP's recommendations are developed by recognized experts in the fields of radiation protection and health effects. The NCRP is a nonprofit corporation chartered by the U.S. Congress to develop and disseminate information and recommendations about radiation protection and to cooperate with the ICRP and other national and international organizations with regard to these recommendations. The ICRP is an international panel of radiation experts from all fields that provides estimates of radiation risk and recommendations on radiation protection and has continued to update and revise its risk estimates and radiation protection recommendations since its inception in 1928. In its deliberations, ICRP maintains relationships with United Nations health and labor organizations.

The IAEA is a United Nations agency involved in assisting member states to establish consistent radiation protection standards. In 1995, the IAEA identified a number of principles with the express purpose of giving a common basis for the development of more detailed standards and a basis for national waste management programs [The Principles of Radioactive Waste Management, IAEA Safety Series No.111-F, International Atomic Energy Agency, Vienna (1995)]. Two of the principles are:

1. Protection of Future Generations. Radioactive waste shall be managed in such a way that predicted impacts on the health of future generations will not be greater than the relevant levels of impact that are acceptable today.

2. Burdens on Future Generations. Radioactive waste shall be managed in such a way that will not impose undue burdens on future generations.

In support of the proposed Part 63 dose limit, the NRC considered other current regulations for consistency and the potential effects of other sources of radiation to select a limit that would be acceptable today for releases of radiation. The EPA, ICRP, and NCRP have all supported the use of source-specific constraints (i.e., a margin of safety) below the 1 mSv/year (100 mrem/year) public dose limit to account for the potential effect of multiple sources of radiation exposure. In addition, use of the critical group concept or the RMEI provides an additional margin of safety because it is difficult for the same individual to be a member of the critical group or to be the RMEI for multiple diverse sources. The final regulations, which specify use of the RMEI concept and limit individual dose to 0.15 mSv/year (15 mrem/year) [15% of the public dose limit], are sufficiently protective that potential exposures from other sources (e.g., past releases from operations at NTS and future hospitals or research centers) would not be expected to result in exposures above the public dose limit.

1. Although an individual might be exposed to more than one source of radiation, it would be a very rare circumstance for that individual to be representative of the population to retain the lifestyle and other characteristics of more than one the RMEI for more than one source.

the individual dose, (2) disagreed with the use of a negligible individual dose value to screen possible release scenarios, and (3) viewed a dose distribution over the population as more informative to the regulators and public, allowing a more risk-informed decision to be made.

Response. The Commission agrees with NAS that "a health-based individual standard will provide a reasonable standard for protection of the general public" (p. 65 of the NAS report). The final regulations, which specify characteristics of a RMEI and an individual dose limit of 0.15 mSv/year (15 mrem/year), are protective of the RMEI. The general public includes the small number of individuals within the RMEI's community as well as all other individuals residing near the Yucca Mountain area. Because the community in which the RMEI resides will have a higher estimated dose than the highest exposed individual who does not live in that community, an individual dose limit for the RMEI is protective of all individuals.

Although ~~while~~ a distribution of individual doses for the entire population arguably can provide more information to consider in making a decision, the speculation and uncertainty regarding a representative population dose distribution would generally make the results inadequate to use in decision making. The difficulty lies in developing the habits, characteristics, location, and exposure time for the entire population. For analyses of possible future releases, such as from degrading waste in Yucca Mountain, the assumptions about the location, habits, and characteristics for each individual (or group of individuals) would be speculative. The Commission believes that it is possible to develop and defend a reasonable exposure scenario for a small group of individuals that would likely receive the largest doses based on current practices in the region because analyzing doses received by the RMEI living in a community at the 18-km (11-mile) location with a diet and living style representative of the people who now reside in the Town of Amargosa Valley, Nevada would bound any doses received by other individuals in the population. Because of the uncertainty in the distribution and range of activities,

including location and number of individuals, for other less exposed groups, unbounded speculation could make any resulting population dose distribution unsupportable.

Although While the Commission could require performance assessments of the potential dose distribution to hypothetical individuals, at the same locations and with the same habits as the current residents, the Commission believes that the uncertainty in the doses calculated for those not subject to the largest expected exposures would make the results difficult to interpret. In the end, the speculation would lead NRC, DOE, EPA, and other interested parties to expend resources without a commensurate increase in public health and safety or protection of the environment.

Collective dose is useful for comparing options but it does not provide adequate protection of the individual. Collective dose is the total dose received by all exposed people, regardless of distance or magnitude of exposure, over all time from a source. In general, most analyses tend to truncate the dose by calculating over a certain time frame and a given environmental area. Truncated collective dose can provide an overall measure of radiological impact on society or on parts of society but is only useful as an aid to compare options (e.g., DOE has considered individuals living within 84 km (52 miles) of the Yucca Mountain site for evaluating population doses in the DEIS). Because the calculation of collective dose results in a single value [in person-Sv (person-rem)], it gives no indication of the range or variability of individual doses or the time when the doses could occur. Meanwhile, the use of an individual dose limit to the RMEI assures that *the vast majority* ~~all other members~~ of the population receive lower doses. The Commission believes that using an individual all-pathway dose assessment provides to the regulator and the public a meaningful measure for making decisions regarding public health and safety.

Issue 4: How is the "As Low As Reasonably Achievable" (ALARA) principle incorporated in Part 63?

Comment. A few commenters suggested that the ALARA principle be explicitly part of the long-term compliance dose limit in Part 63. Others supported the proposed rule for not including the ALARA principle in the requirements for the long-term performance requirements because the cost-benefit analysis would be highly speculative.

Response. The Commission believes that, while it is appropriate to explicitly require the application of the ALARA principle to the operational and decommissioning phases of the repository, the application of ALARA to achievement of long-term performance objective is not.

The ALARA principle deals with optimizing the reduction of potential doses from radiation to members of the general public and workers. It is a principal component of the radiation protection philosophy during operations and decommissioning activities and it helps to ensure that no individual will receive greater than his or her respective annual dose limit [i.e., 1 mSv/year (100 mrem/year) for the public and 50 mSv/year (5,000 mrem/year) for radiation workers]. Application of ALARA, during operations, compels the consideration of the benefits of further reduction in potential doses to present-day populations and workers relative to impacts to present-day populations (e.g., increased cost to reduce potential doses further). The application of ALARA to the achievement of the post-closure performance objective would involve considerations far more complicated than those evaluated for operations. The reasonableness of further reduction of potential doses would need to evaluate benefits and impacts that span many generations (e.g., costs incurred today versus a reduction of potential doses thousands of years in the future; repository designs that reduce potential doses in the future but increase doses to present-day workers during fabrication of the design such as installing a special backfill). By adopting the EPA's dose limit for long-term performance, the Commission implements a

constraint that is a small fraction (15 percent) of the public dose limit, and which provides a significant margin of safety to ensure that public health and safety and the environment are protected.

In its 1995 findings and recommendations, NAS noted that there is no scientific basis for incorporating the ALARA principle into NRC's Yucca Mountain regulations. In summary, their reasoning was that deep geologic disposal, by its very nature, was ALARA, and there were few technological alternatives in repository design. They also noted it would be problematic to evaluate compliance with the application of ALARA principles in the post-closure phase of the repository. The Commission agrees with NAS in this regard. Therefore, ^{although} while the Commission will require ALARA considerations for the operational phase and decommissioning of the surface facilities, NRC will not explicitly require an ALARA analysis as part of the post-closure performance assessment.

Issue 5: Why did NRC select 0.25 mSv/year (25 mrem/year) as the proposed dose limit?

Comment. A large number of commenters addressed the 0.25 mSv/year (25 mrem/year) dose limit in proposed Part 63. A large number either disagreed with the limit, saying it was too high, or supported a lower standard such as the EPA's 0.15 mSv/year (15 mrem/year) standard in 40 CFR Part 191 and proposed 40 CFR Part 197. Some commenters (1) expressed confusion on whether the dose limit was for workers or members of the public, (2) requested additional clarification on what "fully protect" meant as part of the dose limit, or (3) supported the 0.25 mSv/year (25 mrem/year) dose limit.

Response. The purpose of the post-closure dose limit and the performance assessment is to ensure that future generations will be adequately protected. EPA has established, and the Commission will incorporate, a dose limit of 0.15 mSv/year (15 mrem/year). The Commission

However, consistent with the EPA standards, the Commission has incorporated a dose limit of 0.15 mSv/yr (15 mrem/yr) in final Part 63.

In the proposed rule, as a point of reference, it stated that the national average background radiation is approximately 3 mSv/yr (300 mrem/yr). Some commenters questioned whether this was valid for the Nevada area considering past practices in the area. The average background radiation stated in the proposed rule did not include variations due to the geology, relative altitude above sea level, or past practices in the region around Yucca Mountain. The Commission does not consider dose from the residual radioactivity left by past practices to be part of the background radiation and notes that EPA specifically accounted for these sources potentially exposing the RMEI in selecting the relevant dose limits for inclusion in its standards for Yucca Mountain.

3.3 Calculation of Expected Dose

Issue: Is the "expected annual dose" an appropriate quantitative measure for demonstrating compliance?

Comment. The public noted that while a specialist may know that the "expected dose" and the "mean dose" are equivalent, to many people "expected" implies the most likely outcome. The same commenter asserted that the mean value derived from the performance assessment is not the most likely, but rather a value that is unlikely to be exceeded. The commenter sought clarification on whether the "expected annual dose" is the mean or the median dose or some other statistical measure. Some members of the public approved of the use of the mean dose rather than the median or mode and noted that mean should provide a reasonable degree of conservatism. Furthermore, some commenters asserted that use of the "expected annual dose"

preliminary analysis of the proposed repository at Yucca Mountain (Mohanty, S., R. Codell, R. Rice, J. Weldy, Y. Lu, R. Byrne, T. McCartin, M. Jarzempa, and G. Wittmeyer, "System-Level Repository Analyses using TPA Version 3.2 Code," Center for Nuclear Waste Regulatory Analyses, CNWRA 99-002, August 1999) indicates that the mean exceeds the 95th percentile at early times (i.e., less than 600 years), the 80th percentile prior to 6,000 years and greater than the 70th percentile at 10,000 years. For this reason, NRC does not believe that addition of a 100-mrem limit on the 95th percentile would provide significant additional protection to the public.

3.4 Infant and Children Dose Standard

Issue: Is the dose limit protective of children (and other sensitive populations) and the environment?

Comment. Many commenters were concerned that the dose limits in Part 63 may not be sufficiently protective of sensitive populations such as children or infants that may be more susceptible to the effects of radiation. Others were concerned that by focusing the dose limit on protecting humans, the environment was not adequately protected.

Response. The international community and the Federal agencies (including EPA) agree ^{follow} ICRP's current guidelines that the overall annual dose to members of the public from all sources that the overall annual public dose limit from all sources should be 1 mSv (100 mrem), which is ^{in order to} not exceed ^{be} protective of all individuals and the environment. The purpose of the public dose limit is to limit ^{These guidelines also hold the exposure} the lifetime risk from radiation to a member of the general public. The conversion factor used to ^{from a} equate dose into risk is based on data from various populations exposed to very high doses of ^{single practice} radiation such as the atomic bomb survivors, and these populations contained individuals of all ^{should be limited to a fraction of this overall dose} ages. Therefore, variation of the sensitivity to radiation with age and gender is built into the standards which are based on a lifetime exposure. A lifetime exposure includes all stages of life,

from birth to old age. For ease of implementation, the radiation standards, which are developed to minimize the lifetime risk, limit the annual exposure that an individual may receive.

Consequently, the limit of 0.15 mSv/yr (15 mrem/yr), which is a small fraction of the annual public dose limit, is protective of children as well as other age groups, because the variation of sensitivity with age and gender was accounted for in the selection of the lifetime risk limit, from which the annual public dose limit was derived. For more information on the selection of the 0.15 mSv/yr (15 mrem/yr) limit, see the discussion under the Individual Dose Limit.

Experimental studies have shown that many flora and fauna tend to be much more resistant to radiation than humans. Therefore, except in cases where large concentrations of radionuclides can enter the environment and no reasonable exposure scenarios exist for humans, one of the principles of radiation protection is that by protecting the public, the environment is protected. In the case of Yucca Mountain and long-term releases, the primary pathway will be through the ground water. ^{Although} While the contaminated ground water may rise up to the surface environment around Ash Meadows (approximately 40 km (25 miles) from Yucca Mountain), the contaminants will ^{be} have been diluted to much lower concentrations than those used in calculating the dose to the RMEI. Therefore, if the RMEI is protected from doses in excess of the dose limit, the environment is also protected.

Should we?
Provide
reference

The International Community and the Federal Agencies regularly review the basis for the public dose limit to evaluate whether new information would suggest a change in the public dose limit. Should the public dose limit in Part 20 change, NRC would evaluate if changes to Yucca Mountain's dose limit are necessary.

consideration of the local biosphere, using the "critical group approach" specified by the ICRP and employing "cautious but reasonable assumptions." The ICRP has generally defined the critical group to be a relatively homogenous group of people whose location and habits are such that they are representative of those individuals expected to receive the highest doses as a result of radionuclide releases (International Commission on Radiological Protection, "Recommendations of the ICRP," *Annals of the ICRP*, Vol. 1, No. 3 [1977]. [ICRP Publication 26] and International Commission on Radiological Protection, "Radiological Protection Principles for the Disposal of Solid Radioactive Waste," Pergamon Press, Oxford, 1985. [ICRP Publication 46])

Both EPA and NRC have identified the ground-water pathway as the most likely pathway for radiological exposures at Yucca Mountain. EPA's standards, which specify the location for the RMEI at 18 kilometers in the predominant direction of groundwater flow, is consistent with the most likely pathway for radiological exposure. This location is generally considered the nearest location to Yucca Mountain where farming activities can reasonably be expected to occur. At distances less than 18 km to the Yucca Mountain site, there is evidence of intermittent or temporary occupation in modern (historic) times in and around the site – for prospecting or ranching [see "Preliminary Performance-Based Analyses Relevant to Dose Based Performance Measures for a Proposed Geologic Repository at Yucca Mountain," T. McCartin and M. Lee (eds.), NUREG-1538, 2001 (in press)]. There are also a number of Native American archeological sites reported throughout NTS closer to the site than the Lathrop Wells location. However, the literature indicates that these were never permanently occupied, and most were abandoned by the end of the 1800's. Overall, the literature suggests many reasons for the absence of permanent inhabitation at distances much closer than 18 km to the site – unfavorable agricultural conditions, inhospitable terrain, the scarcity of mineral resources, and limitations on water availability.

As discussed in the proposed regulation, farming activities are considered to be representative of those individuals expected to receive the highest dose because (1) farming activities involve more exposure pathways than other known human activities in the region (e.g., ingestion pathway through consumption of contaminated water, crops, and animal products) and (2) the relatively large water demand for ground water for irrigation increases the likelihood of drawing contaminated water to the surface where human exposures could occur (64 FR 8645; February 22, 1999).

Finally, with regard to the suggestion that the NRC staff's understanding of drilling and pumping practices in the area is outdated, the Commission does not share this view. Rotary drilling technology, first introduced into the U.S. in the early 1900's, is still used to drill most wells in the U.S., including those in the Amargosa Desert area. The Commission is also aware that there are now more efficient submersible pumps capable of pumping ground water from greater depths. However, the costs of developing deep ground-water resources increase proportionally with depth, regardless of pump efficiencies.

Issue 2: Should alternatives to the proposed farming community critical group be considered?

Comment. A few commenters objected to the NRC staff's proposed farming community critical group type and noted that parameters used by the NRC staff to define it were themselves controversial and speculative. Overall, the commenters recommended that the NRC staff give more consideration to the criteria used to define the characteristics of the critical group and, in doing so, other critical groups could be identified and situated at locations closer than 20 km to the proposed repository. A question was also raised whether doses would be higher if a farming critical group were located closer than 20 km to Yucca Mountain.

more attractive and led to diversification of the local economic base which now includes a dairy, a turf farm, a hotel, a casino, and a golf course. The availability of commercial electricity has also led to a moderate increase in the permanent, non-farming resident population. Non-farming activities, as one commenter pointed out, are generally unaffected by ground water depth, soil type, and other similar factors and could take place anywhere in the Yucca Mountain area, but have not, because the lands immediately surrounding Yucca Mountain are Federally owned. It is likely that in addition to the existence of infrastructure (roads and commercial electricity) other factors as significant as the physical ones, have also contributed to diversification of the local economic base in Amargosa Valley. However, decisions to pursue diverse business ventures are typically made privately, by business persons or corporations, taking into account economic forces in the market place. In the Commission's view, it is impossible to predict the future behavior of the national or local economy and translate this behavior into specific human actions in the Yucca Mountain area.

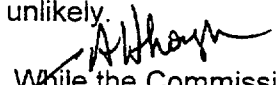
In summary, the requirement that the RMEI use water of average contaminant concentration, in a volume of water (3,000 acre-feet) reflective of a farming community, is conservative. Because the RMEI is defined as that person reasonably likely to receive the highest doses, the selection of RMEI characteristics must take into consideration both the magnitude of the dose likely to be received and the likelihood that a dose will actually occur at that location. The Commission believes that EPA selected the characteristics of the RMEI based on cautious and reasonable assumptions for the community of individuals likely to receive the highest doses. For these reasons, the Commission has adopted EPA's definition of the RMEI, as it appears at 40 CFR 197 and added the additional requirement for water usage by the RMEI.

3.6 Critical Group Characteristics and Reference Biosphere

Issue 1: Is the average member (of a critical group) an appropriate measure to protect public health and safety?

Comment. A number of commenters focused on the proposed approach of calculating doses to an average member of a critical group. Commenters noted: (1) use of the average member results in some people (aside from those with extreme habits) receiving less protection than others (i.e., individuals protected by assuming current conditions may not be protected under potentially different future conditions); (2) the proposed rule does not provide a definition of the average member of the critical group; (3) the appropriate measure is the average of calculated doses to members of the critical group rather than a single dose calculated for a single member with average characteristics; and (4) a subset of the farming group that would be more likely to experience health effects (e.g., children) should be used.

A few commenters suggested use of a subsistence farmer. One commenter added that sensitivity studies should be done for a subsistence farmer (i.e., all food locally grown) located closer than 20 km from the proposed repository site to gain insights into risk, even though such a scenario would be unlikely.

Response.  While the Commission finds that limiting the dose received by the average member of the critical group is protective of current and future populations in the vicinity of the site, the final rule has been changed, as required by EnPA, to use 40 CFR 197's mean dose to the RMEI as the measure to compare with the dose limit. The RMEI approach has been characterized as providing a similar level of protection to that achieved by protecting the average member of the critical group, as was proposed for Part 63. In its comments to EPA on the proposed 40 CFR 197, the NAS noted that the reasonably maximally exposed individual is very

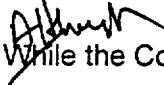
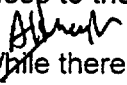
similar to the internationally used critical group approach. Additionally, NRC quoted, in the proposed rule, the International Commission on Radiological Protection which stated that it may be convenient to define the critical group in terms of a single hypothetical individual. The International Atomic Energy Agency's (IAEA's) Biosphere Modeling and Assessment working group has taken it further and calls such a hypothetical individual a reasonably maximally exposed individual (BIOMASS, 1999). ^{Alkhan} While there are slight differences between the EPA's reasonably maximally exposed individual and NRC's proposed average member of the critical group, they are virtually the same (especially in view of the IAEA's guidance). As noted earlier, the Commission has adopted the RMEI approach to be consistent with 40 CFR 197.

The issue of whether children are protected has been taken into consideration in developing the rule (see discussion under Infant and Children Dose Standard). In summary, the standards were developed with sufficient conservatism to protect all members of the public regardless of age or gender.

The Commission disagrees with the recommendation that the NRC should use the admittedly unlikely subsistence farmer approach as the basis to test sensitivities (for additional information on the subsistence farmer approach, see the response to Issue 2, below). The NRC expects that sensitivity studies based on unrealistic and unlikely exposure scenarios would provide results that would be difficult to interpret and relate to the actual anticipated conditions of exposure. The NRC, however, agrees with the commenters' recognition of the value of sensitivity analysis as a tool to gain insight into uncertainties and the importance of parameters and models. NRC conducted extensive sensitivity analyses with an independently developed total performance assessment code (Nuclear Regulatory Commission. Sensitivity and Uncertainty Analysis for a Proposed Repository at Yucca Mountain, Nevada, Using TPA 3.1,

community is conservative (i.e., protective). One commenter questioned the accuracy of the reported population count for Amargosa Valley.

Some commenters suggested alternative critical groups as being more representative or protective of the local population. Representatives of the Western Shoshone people suggested their long existence in the region and lifestyle in close proximity to the land support selection of a Western Shoshone critical group. They noted a long history of a hunting and gathering "subsistence" lifestyle that is expected to remain into the future. Farming and livestock activities were also discussed as recent introductions to the Western Shoshone lifestyle.

Response.  While the Commission considers the proposed assumptions about the characteristics of the critical group to be protective of current and future populations in the vicinity of the site, the final rule has been changed, as required by EnPA, to use the mean dose to the RMEI, as defined at 40 CFR 197, as the measure to compare with the dose limit.  While there are slight differences between the characteristics of EPA's reasonably maximally exposed individual and the proposed average member of the critical group, they are practically the same. However, as noted, the Commission has adopted the characteristics of the RMEI, as specified in 40 CFR 197 and added two additional requirements.

Regarding the two additional requirements, the final regulations specify: (1) the water demand to be used in estimating exposure to the RMEI (see response to Issue 2 under Critical Group Location); and (2) that the RMEI is an adult with metabolic and physiological considerations consistent with present knowledge. Specification of the RMEI as an adult is: (1) consistent with the NAS recommendations for specifying the exposure scenario by rule; (2) consistent with the proposed regulation characteristics for the exposure scenario; (3) consistent with the criteria for the RMEI specified in the EPA standards (i.e., drinks 2 liters of water per day); and (4) consistent with the EPA's Draft Federal Radiation Protection Guidance for Exposures of

replaced with the RMEI for consistency with EPA's standards.

~~Although~~
While it is beyond the capabilities of present-day science to determine "with certainty" that a future ice age will occur, the present paleoclimatic data support that (1) ice ages have occurred in past history, (2) climate changes in the past have exhibited a cyclical pattern, and (3) the cycle is likely to lead back to another ice age. The NRC has extensively investigated relevant research on future climate change in the vicinity of Yucca Mountain and has summarized the available information in an Issue Resolution Status Report (Nuclear Regulatory Commission. Issue Resolution Status Report Key Technical Issue: Unsaturated and Saturated Flow Under Isothermal Conditions, Revision 2, Vol 1. Washington DC: Nuclear Regulatory Commission, June 1999). The Commission encourages members of the public who are interested in the topic of past and future climate change in the vicinity of Yucca Mountain to obtain a copy of this report from the NRC Public Document Room (PDR) or from the NRC website

~~(www.nrc.gov/NMSS/DWM/usfic.html)~~. (For more information about obtaining reports from the NRC PDR, mail a request to U.S. Nuclear Regulatory Commission, Public Document Room, Mail Stop O1F13, Washington DC 20555, or e-mail pdr@nrc.gov.) The NAS committee was also familiar with the science behind future climate changes and stated, in its recommendations on Yucca Mountain standards, that a future ice age in the next few hundred years is unlikely but not impossible, in the next 10,000 years is probable but not assured; however, over a million-year time frame, the climate is virtually certain to pass through several glacial-interglacial cycles (i.e., ice ages). The Commission believes there is sufficient information in the paleoclimate record to justify including climate change in the final regulations regarding effects on repository performance.

Climate change was included in the proposed regulations for the reference biosphere in § 63.115 because the NRC believed there was sufficient scientific evidence supporting the

potential for climate change over the long time frames considered by the performance assessment calculations. ^{Although} While NRC analyses suggest that inclusion of climate change in the biosphere is not likely to significantly change the local climate conditions and assumed exposure conditions, the Commission believes it is important to include the consideration for climate in both the geosphere and the biosphere performance assessment calculations to ensure that the conceptual model of the environment is consistent with our scientific understanding of reasonably anticipated natural events such as climate change. The NRC also believes it is important for DOE to include these processes in their performance assessment calculations and do the necessary technical analyses to ensure the processes have been adequately considered and addressed.

The NRC agrees there is a need to emphasize current conditions when applied to behavioral characteristics of the RMEI. The natural systems of the biosphere are allowed to vary (e.g., climate change) because the geologic record provides evidence of past climate over a long time frame, which provides a strong basis for predicting future changes. Because human behavior cannot be similarly predicted, a similar approach cannot be used for the RMEI and the influence the local population has on the biosphere. Thus, a need exists to emphasize current conditions for the RMEI (see response to Issue 1 for more information). The suggestion that NRC consider alternative futures related to human behavior is speculative and leads to problems deciding which alternative futures are credible and which ones are unrealistic. Such issues have no scientific or technical answer. It is DOE's responsibility to demonstrate that the RMEI and biosphere assumptions in performance assessment calculations are consistent with local conditions. During the review of the license application, the NRC will evaluate DOE's assumptions to ensure they are consistent with current information. Given the uncertainties associated with local economics, NRC believes it is unreasonable to expect DOE to predict future

dose limit of either 0.15 mSv (15 mrem) or 0.25 mSv (25 mrem) TEDE ensures that the risks provide greater
all radionuclides and all exposure pathways, including the ground-water pathway, are acceptable the quantity
and protective. The EPA, itself, acknowledged, in publishing final standards for Yucca Mountain,
that an "...Individual Protection Standard is adequate in itself to protect public health and safety."
However, ultimately, the EPA has to make the decision whether to include separate requirements
for groundwater protection and the final EPA standards for Yucca Mountain include such
requirements. ~~for the purpose of protecting ground water~~ Therefore, as required by law, final Part 63 requirements incorporate final EPA
standards for Yucca Mountain at 40 CFR 197, including separate ground water protection
requirements. These requirements, §§ 197.30 and 197.31, appear in the final regulations as
§§ 63.331 and 63.332, respectively.

3.8 Multiple Barriers and Defense-in-Depth

Issue 1: Should NRC set quantitative limits (that is, subsystem requirements) for specific barriers that make up the repository system?

Comments. The NRC received comments, both supporting and opposing the approach proposed in Part 63, to provide a single overall, health-based, performance objective and avoid setting arbitrary, quantitative limits on individual barriers. Commenters in favor of a single system performance goal stated that risk-informed and performance-based regulations allow the applicant and the regulator to place greatest emphasis on issues important to health and safety. Commenters supporting quantitative limits for specific subsystems expressed concern that reliance on quantitative performance assessments to show compliance with a single measure of performance is less protective than setting specific numerical criteria for the performance of individual barriers. They argued that quantitative limits for individual barriers are needed to

results for estimating long-term repository performance. They also obviate, in the Commission's view, the need to prescribe arbitrary, minimum performance standards for subsystems to build confidence in a system's overall performance.

The Commission's goal is to protect public health and safety and to ^{an}assure compliance with EPA's standards. NRC's evaluation of DOE's compliance demonstration will examine how all components of the repository system work together to achieve this goal. Therefore, the proper emphasis should not be on the isolated performance of individual barriers but rather on ensuring the repository system is robust, and is not wholly dependent on a single barrier. Further, the Commission supports an approach that would allow DOE to use its available resources effectively to achieve the safest repository without unnecessary constraints imposed by separate, additional subsystem performance requirements. It is also important to remember that Part 63 requires DOE to carry out a performance confirmation program to provide further confidence that barriers important to waste isolation will continue to perform as expected (see Section 2.4 on Performance Confirmation).

Issue 2: How does the multiple barrier provision fulfill NRC's defense-in-depth philosophy in evaluating repository performance?

Comments. Some commenters asked the NRC to explain how we apply defense in depth to the repository without specific calculations or numerical limits for meeting this requirement. They stated that the proposed Part 63 is not clear about how DOE must demonstrate defense in depth for repository performance.

Response. In general, the Commission believes that a repository system should reflect the philosophy of defense in depth. The Commission expects that if a repository system is made up of multiple barriers, then it will be more tolerant of unanticipated failures and external

challenges. The final regulations specify criteria for quantitatively evaluating post-closure performance (e.g., individual protection, ground-water protection, and evaluation of human intrusion). These criteria help ensure defense in depth by requiring calculations that provide risk insights into the impact on performance of specific system attributes and external conditions. DOE must evaluate the performance of the repository system, as it performs as a result of compliance with general design criteria (e.g., required use of multiple barriers and identification of the repository by markers). DOE must also evaluate the system's response to various external challenges (e.g., disruptive events treated in the performance assessment, as well as a specified human intrusion scenario).

Commenters on the proposed rule pointed out that neither the intent of the multiple barrier provision, mandated by the Nuclear Waste Policy Act, nor how NRC would decide compliance with this provision, were clear. To clarify this intent, the final rule explains the concepts associated with the multiple barrier provision in § 63.102, and provides the associated technical criteria in § 63.115.

The proposed rule would have required DOE to: (1) identify barriers; (2) describe quantitatively each barrier's ability to contribute to waste isolation; and (3) provide technical bases for the barriers' capabilities as part of the overall demonstration of compliance with the individual protection standard (see § 63.114 (h)-(j) of the proposed rule). Although not necessarily required as a separate demonstration, this required information on the capability of barriers, integral to the performance assessment, illustrates the resilience, or lack of resilience of the repository to unanticipated failures or external challenges. Also, quantitative insights about defense in depth of the proposed repository emerge directly from the quantitative evaluations in the performance assessment. The performance assessment must include analyses of the effects of unlikely, but credible, external challenges on overall performance (In its analyses, DOE

must consider disruptive events that have an annual probability of occurrence greater than 10^{-8}). Disruptive events may degrade performance of the engineered barriers or reduce the effectiveness of natural barriers or both. Also, DOE must evaluate uncertainty about the performance of engineered barriers and that of the natural barriers in the performance assessment. For example, uncertainty about the corrosion rate of the waste package will necessarily affect the estimated lifetime of the package. Likewise, uncertainty about geochemical sorption will affect estimates of the time it takes specific radionuclides to travel in the geosphere. As with the disruptive events, the proper consideration of uncertainty in the performance assessment should ^{en} assure an evaluation of the range of response of individual barriers to various challenges (e.g., higher than normal corrosion rates, lower than normal geochemical sorption). Thus, a complete performance assessment (*i.e.*, one that complies with §63.114) will illustrate the effectiveness of the multiple barriers, and the implementation of the philosophy of defense in depth, such that the individual protection standard is shown to be met even when barriers are challenged.

The Commission has clarified how DOE is to develop the technical basis for each barriers technical capability. The change makes clear that a description of relevant information, about a given barrier's characteristics and performance, that DOE has used to support the overall performance assessment, is sufficient to show compliance with this requirement. The language of the proposed rule was not intended to imply that an acceptable technical basis for multiple barriers need be (or even could be) derived separately from the basis for the performance assessment, itself. Rather, the technical basis for the barriers should be a presented in a focused, clear description. This description should be derived from pertinent information contained in the technical basis for the performance assessment.

particular barriers at Yucca Mountain, or at any other site, independent of the complex repository system in which they must perform. The Commission is confident that evidence for the resilience, or lack of resilience, of a multiple-barrier system will be found by examining a comprehensive and properly documented performance assessment of the behavior of the overall repository system. Such an assessment must consider credible and supportable ranges of individual parameters and modeling assumptions, and must include multiple evaluations of a wide range of combinations of resulting barrier performance.

Finally, the required description of barrier capability provides information that will aid in the interpretation of the performance assessment results, while at the same time providing information that is independent from the condition of the other barriers. For example, the unsaturated and saturated zones could provide significant retardation to many radionuclides such that radionuclides will not reach the RMEI within 10,000 years regardless of when the waste package fails. This capability of geologic systems to "retard" or slow the movement of contaminants is present, and provides defense in depth, even when releases from the waste package are not occurring. Describing the capabilities of the system's component barriers (e.g., retardation of specific radionuclides in specific geologic media) can be accomplished by describing the applicable conceptual models and parameters used in the performance assessment. It does not require quantitative calculations beyond those performed to demonstrate compliance with the post-closure performance objectives. The Commission believes that understanding the capability of the system's component barriers provides an understanding of the repository system that can increase confidence that the post-closure performance objectives are met. The Commission is satisfied that the clarifying additions discussed above, along with other requirements at §§ 63.114 and 63.115, if met, will provide sufficient basis to determine whether a proposed repository system acceptably provides a system

of samples and data, scientific studies, performance of tests and experiments, controlling geological and engineering materials samples, facility design and equipment construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities. These terms are defined in § 63.2.

Based on the above discussion, the NRC considers the applicability of the QA program to be adequately described in Subpart G to Part 63. Because proposed Part 63 referred to Appendix B for QA requirements and Appendix B does not use the terms important to safety and important to waste isolation, requirements from Appendix B ^{are} ~~will be~~ incorporated into final Part 63, ~~and~~ modified accordingly to address their applicability to the high-level waste repository.

Issue 7: Should Part 63 contain QA program change controls similar to those found in § 50.54(a), and should the proposed § 63.44 change control process be applicable for QA program changes?

Comment. DOE identified a problem with proposed Part 63 requirements for controlling changes to the QA program and recommended that requirements similar to those contained in § 50.54(a) be used. DOE correctly pointed out that the NRC stated, in the discussion accompanying the final rule for Part 50 concerning changes to QA programs (64 FR 9030; February 23, 1999), that "use of 10 CFR 50.59 criteria for QA program changes is not appropriate." DOE pointed out that, as written, proposed Part 63 would permit QA program changes to be controlled in accordance with requirements similar to § 50.59 (as permitted by § 63.44). DOE suggested text changes to implement its comments. DOE also expressed a concern that as proposed, the location of § 63.21(c)(11) would cause the QA program description contained in the Safety Analysis Report to be subject to the change controls required by § 63.44.

Response. The Commission agrees that the use of the criteria specified at § 63.44 is not

matter, and, consistent with its obligations under law, has adopted the dose limits published by EPA in its standards for Yucca Mountain.

Issue 2: Will there be more public meetings?

Comment. Commenters stated that it would be helpful for NRC to consider increasing its efforts in the area of public outreach and commit to hold more public meetings in the future. Another commenter suggested that the NRC program focus should be on public health and safety and not on political issues associated with the HLW program.

Response. The Commission agrees with the recommendation to increase its efforts in the area of public outreach. The NRC staff will continue to hold public meetings in Nevada. We continue to seek a better understanding of the views and concerns of the public on how we can best fulfill our independent regulatory responsibility to protect public health and safety.

As far as avoiding political issues associated with the Yucca Mountain site, the Commission notes that it has taken no position on the suitability of Yucca Mountain to host a potential geologic repository. That decision rests with DOE, with the subsequent approval of the President and Congress.

Issue 3: What is the role of NRC's local office in Nevada?

Comment. Some commenters asked if NRC had a local office in Nevada and if there was one, how could the public contact the staff there. One commenter suggested that the role of the local office be expanded to represent NRC in a manner more visible to the public.

Response. NRC maintains a local onsite representative's office, with a small staff, in Las Vegas, Nevada, as a means of keeping abreast of DOE activities ^{and interacting with other stakeholders} at the Yucca Mountain site. This office allows our onsite representatives physical proximity to the site and the opportunity to

~~On various~~
interact with the principal DOE staff engaged in site characterization activities. At this time, the NRC has no plans to expand the size of the onsite representative's office. However, the size of the office, as well as the scope of NRC's activities conducted there, is subject to reexamination. Meanwhile, the public is encouraged to contact our staff at the onsite representative's office at:

1551 Hillshire Drive, Suite A

Las Vegas, Nevada 89137-1048

Telephone 702/794-5046

Issue 4: Should AULGs and EPA be included in the regulations at Part 63, Subpart C, §§ 63.61 - 63.65, providing for participation in certain NRC regulatory activities?

Comment. One local government commenter noted that, under the NWPAA, there is a legal basis for the participation of affected units of local government (AULGs) in activities concerning a potential repository at the Yucca Mountain site and asked why AULGs have not been included in § 63.61 and subsequent sections dealing with participation in regulatory activities. Another local government commenter explicitly requested that AULGs be included in the requirement for provision of "timely and complete information" in § 63.61. EPA also requested that it be included in § 63.61(a) given its interest in the proper implementation of the standards.

Response. Section 116(c) of the NWPAA directs DOE to provide funding to AULGs so that they may participate in activities required or authorized under sections 116 and 117 of the NWPAA. ^{Although} While these activities primarily involve DOE's interactions with the State, affected Indian tribes, and AULGs, the Commission believes that it would not be inconsistent with the intent of the statute to include AULGs at appropriate points in the regulations under Part 63, Subpart C, and has revised the regulations accordingly. The Commission is not adding EPA to §

Part 2, Subpart J, "Procedures Applicable to Proceedings for the Issuance of Licenses for the Receipt of High-Level Radioactive Waste at a Geologic Repository" (Subpart J) (54 FR 14925; April 14, 1989). Section 2.1014(c) of Subpart J permits intervention of AULGs in a repository licensing proceeding without the need to establish "party" status:

"Subject to paragraph (a)(3) of this section, the Commission, or the Presiding Officer designated to rule on petitions to intervene and/or requests for hearing shall permit intervention, in any hearing on an application for a license to receive and possess high-level radioactive waste at a geologic repository operations area, by an affected unit of local government as defined in section 2(31) of the Nuclear Waste Policy Act of 1982, as amended, 42 U.S. 10101." [§ 2.1014(c) (1999)]

See also the definition of "party" in § 2.1001 which, as amended in 1998 (63 FR 71729; December 30, 1998), defines a "party" to mean the DOE, the NRC staff, the host State, any AULG as defined in section 2 of the NWPA, any affected Indian Tribe as defined in section 2 of the NWPA, and a person admitted under the criteria in § 2.1014. These regulations relieve the State, affected Indian Tribes, and AULGs from the need to meet the standing requirements in order to be admitted as a party in the proceeding. The State, an affected Indian Tribe, and an AULG must still submit contentions in accordance with the provisions of § 2.1014(a)(2)(ii) and (iii), and at least one contention must satisfy these requirements, or the State, affected Indian Tribe, or AULG shall not be permitted to participate as a party. [§ 2.1014(a)(3) (1999)]

All of the above is in the context of the existing hearing procedures in Part 2. The Commission recently proposed revisions to Part 2 (66 FR 19610 (April 16, 2001)). Even under the proposed revisions, however, a "party" in a Subpart J proceeding continues to be defined as including the host State, any affected unit of local government and any affected Indian Tribe, provided that these entities file an acceptable contention. Thus, the Commission has not

Sketch

The NRC staff will continue to provide information to explain the risks that would be associated with a repository licensed in accord with its regulations by using a variety of comparisons. ~~The potential health effects arising from any radiation exposure is a very complex subject.~~ To provide a context for NRC's proposed criterion of 0.25 mSv/yr (25 mrem/yr) or EPA's final limit of 0.15 mSv/yr (15 mrem/yr) individual dose limit for Yucca Mountain, NRC staff members frequently draw comparisons with other dose limits applied in NRC's regulation for low-level waste disposal (Part 61) as well as with national and international recommendations for radiation standards (see discussion under Individual dose limit). To provide some context for understanding what a radiation exposure at these levels represent, ^S comparisons have been made to the values for more "routine" radiation exposures (e.g., dental x-rays, increased radiation exposure from traveling in a plane). These comparisons are used to inform the public, not to persuade them.

With respect to the meaning of the term "individuals with unusual habits and sensitivities," the Commission believes the commenter refers to the findings and recommendations of NAS. Both these recommendations and final EPA standards require that DOE base the characteristics of the representative group for post-closure dose calculations (the community in which the RMEI resides) on lifestyles and dietary habits (i.e., reliance on well water, extent to which food is grown locally, types of foodstuffs eaten) of individuals currently living in the Yucca Mountain region. NAS explained that specification of the representative group should avoid extreme cases defined by unreasonable assumptions regarding the factors affecting dose. NAS also stated that a reasonable and practicable objective is to protect the vast majority of members of the public while also ensuring that the decision on the acceptability of a repository is not prejudiced by the risks imposed on a very small number of individuals with "unusual habits or sensitivities" (pp. 51-52, "Technical Bases for Yucca Mountain Standard," National Research Council, 1995). Hence, the

terms "unusual habits" and "sensitivities" were used to exclude unreasonable assumptions about the ~~from~~ the characteristics of a hypothetical, future population group or RMEI. ~~The Commission~~ is quite certain that the NAS did not use these words to imply any judgment with regard to the behaviors or mental state of individuals residing near the site today. The Commission will continue to strive to explain more clearly ~~complex technical and regulatory issues,~~ *the risks associated with the Yucca Mountain potential repository at*

for safety.

Issue 7: In the future, how is the NRC going to effectively communicate the risks of the Yucca Mountain Project to public health and safety?

Comment: One commenter requested one-on-one contact answering calls and letters and following through with questions and sending written responses. Another commenter was concerned that the people of Nevada are not suitably informed about the risks involved with the Yucca Mountain Project. Also, one commenter suggested that a bulletin be published quarterly or as an insert to a local paper about the Yucca Mountain Project. A few commenters were concerned that their fears are considered "irrational" regarding the safety of the Yucca Mountain Project and will not be taken seriously.

Commenters suggested that NRC use "local" sources (e.g., local government and libraries) to provide information to the public regarding meetings and other information. Information should be written in plain English.

Response: The NRC understands the importance of a strong public outreach program. NRC held five public meetings in Nevada during the public comment period on proposed Part 63. Comments made at those meetings were instrumental in NRC deciding to extend the public comment period for the proposed rule. However, these meetings also demonstrated to NRC that ~~we can and need to do better in our~~ *it improve its* public outreach efforts. The NRC has held seven additional public information workshops in Nevada since the public comment period closed on Part 63. We

will continue to meet with the people of Nevada and continue to seek the public's views on how we can carry out our responsibilities in a more effective manner. We also intend to keep the public better informed about our independent regulatory activities and oversight. The NRC will also continue to work on providing displays and fact sheets that use plain English.

The Commission notes also that DOE maintains three visitor centers that are intended to keep the public informed. They are located in Beatty, Pahrump, and Las Vegas. DOE also sponsors regular field trips to the Yucca Mountain site itself. ~~lastly~~, DOE maintains an Internet web page with information that is regularly updated on activities at the site and developments in the program; it can be found at <http://www.ymmp.gov>. With regard to the comments proposing that activities and future events be published in local newspapers, the NRC staff will forward that recommendation to DOE. As the repository developer, DOE has the responsibility to keep interested members of the public informed about activities at the site as well as about the program. For those that are interested, the State of Nevada, Nye County, Clark County, Eureka County, Inyo County, California, and others also maintain web sites with information about the Yucca Mountain program. They are located, respectively, at <http://www.state.nv.us/nucwaste>, <http://www.nyecounty.com>, <http://www.co.clark.nv.us/complan/Nucwaste.htm>, <http://Yuccamountain.org> and <http://sdsc.edu/Inyo/yucca-pg.htm>.

Finally, the Commission notes that the NRC staff has maintained a schedule of meetings with DOE on its web page (<http://www.nrc.gov/nmss/dwm/hlw/hlm>) for several years. Important NRC documents related to the HLW program are also distributed to DOE. Effective November 1, 1999, NRC is making HLW program documents generated and received available on its Electronic Public Reading Room located at <http://www.nrc.gov/nrc/adams/index.html>. Documents generated prior to November 1, 1999, can currently be found at the designated library reading rooms (in Nevada).

to DOE, the state, and attached units of local government and other stakeholders.

Issue 8: How do the NRC and DOE, both as government agencies, maintain a proper relationship, respectively, as the regulator and a potential licensee?

Comment. One commenter was concerned that constant care needs to be taken by both NRC and DOE to maintain a relationship that clearly delineates between the regulator and the licensee.

Response. The NRC is developing a regulatory framework for the licensing of the proposed high-level waste repository with the promulgation of Part 63 and development of the Yucca Mountain Review Plan. This framework will clearly define the geologic disposal regulations DOE must meet and provide specific guidance to DOE on the information and evaluations necessary to demonstrate compliance with the regulations. As an independent regulatory agency, NRC's overall safety mission is to protect public health and safety, the environment, and common defense and security. NRC's regulatory role in any licensing action is to apply the applicable regulations and guidance, and to review applications for proposed actions to determine if compliance with regulations has been achieved.

The NRC Safety Philosophy will be applied to DOE's license application. This basic NRC Safety Philosophy, which is applicable to all the agency's licensing actions, is found in NRC's Strategic Plan. The underlying regulatory philosophy used by NRC in conducting its regulatory mission can be found in the section "Licensee Responsibility," which states the following:

"LICENSEE RESPONSIBILITY embodies the principal that, although NRC is responsible for developing and enforcing the standards governing the use of nuclear installations and materials, *it is the licensee who bears the primary responsibility for conducting these activities safely. The NRC's role is not to monitor all licensee activities but to oversee and audit them* [emphasis added]. This allows the agency to focus its inspection, licensing,

and other activities on those areas where the need, and the likely safety and safeguards benefit, are greatest."

To state it more succinctly, the safe operation of any nuclear facility is the responsibility of the licensee. This philosophy is an important foundation for how the NRC staff is to conduct its reviews in general, and licensing reviews in particular. Implementing this philosophy means that (1) the NRC does not select sites or designs ~~or participate~~ with licensees or applicants in selecting proposed sites or designs; (2) NRC's role is not to monitor all licensee activities but to oversee and audit them; and (3) the three outcomes available to NRC at the conclusion of a licensing review are: (1) grant the application; (2) grant the application subject to certain conditions agreed upon by the licensee; or (3) deny the application. Other than rejecting an applicant or licensee's proposal, NRC has no power to compel a licensee to come forward or to require a licensee to prepare a totally different proposal. ✓ delete

The interactions of the NRC staff and the DOE staff with respect to all activities preparatory to DOE's submission of a license application are governed by the "Agreement Between DOE/OCRWM and NRC/NMSS Regarding Prelicensing Interactions," which was initially signed in 1983 and was revised in 1998, and by the NRC Staff's Policy Statement on Staff Meetings Open to the Public (59 FR 48340; September 20, 1994). These documents provide that meetings between the two staffs will be open to the public as specified in the Policy Statement and that management commitments will be documented in correspondence subsequent to the interactions. Thus, procedures are in place to ^{en}sure an appropriate open relationship between the potential regulator and the potential licensee.

Issue 9: Should different DOE organizations active in Nevada be required to better coordinate their activities and responses to questions from the public?

word climatological is not needed; therefore, the language in proposed Part 63 will be retained in final Part 63.

6 Beyond the Scope of This Rulemaking

The following comments addressed issues that are beyond the scope of this rulemaking. Many of the comments in this category were directed at the hearing process, transportation, the selection of Yucca Mountain as a potential site for a geologic repository, or objected to deep geologic disposal as a method of managing HLW. Part 63 does not affect these issues because they have already been determined by legislation, are pertinent to other regulations or rulemakings but not to Part 63, or because the provisions of Part 63 are limited to specific regulatory areas while these issues are much broader.

6.1 Hearing Process

Issue: Will the Commission amend the hearing process for repository licensing to provide for informal, legislative-style hearings?

Comment. Some commenters, including EPA, urged NRC to change its hearing process to provide for informal, legislative-style hearings for repository licensing. One commenter suggested that the Commission itself be the hearing board. NEI expressed the view that a legislative-style hearing process is more conducive to effective scientific inquiry than formal adjudicatory procedures. NRC's decision on whether to adopt an informal process for repository licensing, in NEI's view, should not be tied to the generic question whether to revise the overall hearing process but, instead, should be the subject of a separate rulemaking. However, another

into this section rather than merely referencing Appendix B in the rule. The introduction of the language from Appendix B into the final Part 63 has not changed any requirements in the proposed Part 63. This approach specifies the quality assurance requirements and ~~more clearly~~ removes any ambiguity regarding which portions of Appendix B are applicable to Yucca Mountain.

Section 63.143 Implementation.

This section has been revised to reference the criteria at § 63.142 rather than the criteria of Appendix B of 10 CFR Part 50, as applicable.

Section 63.144 Quality assurance program changes.

This section has been added to provide requirements for how changes to the quality assurance program description are to be processed.

Subpart K – Preclosure Public Health and Environmental Standards

Section 63.201 Purpose and scope.

New section that states the requirements in this subpart apply to the storage of radioactive waste in the Yucca Mountain repository and on the Yucca Mountain site.

Section 63.202 Definitions for subpart K.

New section adopted from the final 40 CFR Part 197 that contains definitions of terms as used in subparts K and L.

Subpart L – Public Health and Environmental Standards for Disposal

This subpart contains provisions that are similar to the public health and environmental standards for disposal specified at 40 CFR Part 197.

Section 63.301 Purpose and scope.

This section stipulates that, to the extent that there may be a conflict, the requirements in this subpart take precedence over other requirements in subparts A through J.

Section 63.302 Definitions for subpart L.

This section contains definitions of terms as used in this subpart.


Section 63.303 Implementation of subpart L.

This section provides a functional overview of this subpart.

Section 63.304 Reasonable expectation.

This section defines what is meant by the reasonable expectation concept.

Section 63.305 Required characteristics of the reference biosphere.

 This section specifies characteristics of the reference biosphere to be used by DOE in their performance assessment used to demonstrate compliance with the requirements specified at §§ 63.113(b) and (d).

INDIVIDUAL PROTECTION STANDARD

This section specifies limits on the levels of radioactivity that would be acceptable in a representative volume of ground water found in the accessible environment for up to 10,000 years following repository closure.

Section 63.332 Representative volume.

This section specifies the assumptions DOE will use to estimate the levels of radioactivity in a representative volume of ground water, at a specified point, down-gradient from any geologic repository at the Yucca Mountain site for up to 10,000 years following repository closure.

ADDITIONAL PROVISIONS

Section 63.341 Projection of peak dose

This section specifies that DOE will estimate peak dose and include the results in its Environmental Impact Statement, however, there is no standard that must be met with respect to these peak dose calculations, and that there is no finding that the NRC must make with respect to these peak dose calculations nor may they be the subject of litigation in any NRC licensing proceedings for a repository at Yucca Mountain.

Section 63.342 Limits on performance assessments.

This section specifies how DOE will ~~determine~~ ^{identify} which features, processes, and events will be considered in the dose assessments described in subpart L.

Section 63.343 Severability of individual protection and ground-water protection standards.

(3) Solids into which such liquid wastes have been converted.

HLW facility means a facility subject to the licensing and related regulatory authority of the Commission pursuant to Sections 202(3) and 202(4) of the Energy Reorganization Act of 1974 (88 Stat. 1244).¹

Host rock means the geologic medium in which the waste is emplaced.

Important to safety, with reference to structures, systems, and components, means those engineered features of the geologic repository operations area whose function is:

(1) To provide reasonable assurance that high-level waste can be received, handled, packaged, stored, emplaced, and retrieved without exceeding the requirements of § 63.111(b)(1) for Category 1 event sequences; or

(2) To prevent or mitigate Category 2 event sequences that could result in doses exceeding the values specified at § 63.111(b)(2) to any individual located on or beyond any point on the boundary of the site.

Important to waste isolation, with reference to design of the engineered barrier system and characterization of natural barriers, means those engineered and natural barriers whose function is to provide reasonable expectation that high-level waste can be disposed without exceeding the requirements of §§ 63.113(b) and (c).

Initiating event means a natural or human induced event that causes an event sequence.

Isolation means inhibiting the transport of radioactive material to:

¹These are DOE "facilities used primarily for the receipt and storage of high-level radioactive wastes resulting from activities licensed under such Act [the Atomic Energy Act]" and "Retrievable Surface Storage Facilities and other facilities authorized for the express purpose of subsequent long-term storage of high-level radioactive wastes generated by [DOE], which are not used for, or are part of, research and development activities."

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Federal Register, at which public records of the Commission pertaining to a geologic

repository at the Yucca Mountain site are made available for public inspection.

Radioactive waste or waste means HLW and radioactive materials other than HLW that are received for emplacement in a geologic repository.

Reasonably maximally exposed individual means the hypothetical person meeting the criteria specified at § 63.312.

Reference biosphere means the description of the environment inhabited by the reasonably maximally exposed individual. The reference biosphere comprises the set of specific biotic and abiotic characteristics of the environment, including, but not necessarily limited to, climate, topography, soils, flora, fauna, and human activities.

Restricted area means an area, access to which is limited by the licensee for the purpose of protecting individuals against undue risks from exposure to radiation and radioactive materials. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set aside as a restricted area.

Retrieval means the act of permanently removing radioactive waste from the underground location at which the waste had been previously emplaced for disposal.

Saturated zone means that part of the earth's crust beneath the regional water table in which all voids, large and small, are ~~fully~~ filled with water under pressure greater than atmospheric.

Site means that area surrounding the geologic repository operations area for which DOE exercises authority over its use in accordance with the provisions of this part.

Site characterization means the program of exploration and research, both in the laboratory and in the field, undertaken to establish the geologic conditions and the ranges of those parameters of the Yucca Mountain site, and the surrounding region to the extent

(i) Changing any of the elements of the method described in the SAR (as updated) unless the results of the analysis are conservative or essentially the same; or

(ii) Changing from a method described in the SAR to another method unless that method has been approved by NRC for the intended application, addition or removal.

(3) *Safety Analysis Report (SAR) (as updated)* means the Safety Analysis Report for the geologic repository, submitted in accordance with § 63.21, as updated in accordance with § 63.24.

(4) *Geologic repository operations area as described in the SAR (as updated)* means:

(i) The structures, systems, and components important to safety or ^{barrier} important to waste isolation that are described in the SAR (as updated); and

(ii) The design and performance requirements for such structures, systems, and components described in the SAR (as updated).

(5) *Procedures as described in the SAR (as updated)* means those procedures that contain information described in the SAR (as updated) such as how structures, systems, and components important to safety, or important to waste isolation, are operated or controlled.

(6) *Tests or experiments not described in the SAR (as updated)* means any condition where the geologic repository operations area or any of its structures, systems, and components important to safety, or important to waste isolation, are utilized, controlled, or altered in a manner which is either:

(i) Outside the reference bounds of the design bases as described in the SAR (as updated); or

(ii) Inconsistent with the analyses or descriptions in the SAR (as updated).

(b)(1) DOE may make changes in the geologic repository operations area as described in the SAR (as updated), make changes in the procedures as described in the SAR (as updated),

(d) Consider only events that have at least one chance in 10,000 of occurring over 10,000 years.

(e) Provide the technical basis for either inclusion or exclusion of specific features, events, and processes in the performance assessment. Specific features, events, and processes must be evaluated in detail if the magnitude and time of the resulting radiological exposures to the reasonably maximally exposed individual, or radionuclide releases to the accessible environment, would be significantly changed by their omission.

(f) Provide the technical basis for either inclusion or exclusion of degradation, deterioration, or alteration processes of engineered barriers in the performance assessment, including those processes that would adversely affect the performance of natural barriers. Degradation, deterioration, or alteration processes of engineered barriers must be evaluated in detail if the magnitude and time of the resulting radiological exposures to the reasonably maximally exposed individual, or radionuclide releases to the accessible environment, would be significantly changed by their omission.

(g) Provide the technical basis for models used in the performance assessment such as comparisons made with outputs of detailed process-level models and/or empirical observations (e.g., laboratory testing, field investigations, and natural analogs).

§ 63.115 Requirements for multiple barriers.

Demonstration of compliance with § 63.113(a) must:

(a) Identify those design features of the engineered barrier system, and natural features of the geologic setting, that are considered barriers important to waste isolation.

(b) Describe the capability of barriers, identified as important to waste isolation, to isolate waste, taking into account uncertainties in characterizing and modeling the barriers.

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isolation, and to related activities in its safety analysis report. These activities include: site characterization; acquisition, control, and analyses of samples and data; tests and experiments; scientific studies; facility and equipment design and construction; facility operation; performance confirmation; permanent closure; and decontamination and dismantling of surface facilities. The description must indicate how the applicable quality assurance requirements will be satisfied.

DOE shall include information pertaining to the managerial and administrative controls to be used ^{en} to assure safe operation in its safety analysis report. High-level waste repositories include structures, systems, and components that prevent or mitigate the consequences of postulated event sequences or that are important to waste isolation capabilities that could cause undue risk to the health and safety of the public. The pertinent requirements of this subpart apply to all activities that are important to waste isolation and important to safety functions of those structures, systems, and components. These activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, modifying, site characterization, performance confirmation, permanent closure, decontamination, and dismantling of surface facilities.

(b) Organization. DOE shall establish and execute a quality assurance program. DOE may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of it, but DOE retains responsibility for it.

(1) The authority and duties of persons and organizations performing activities affecting the functions of structures, systems, and components that are important to waste isolation and important to safety must be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the quality assurance functions. The quality assurance functions are those of:

drawings for accomplishing the activity. The inspection must be performed by individuals other than those who performed the activity being inspected.

(1) Examinations, measurements, or tests of material or products processed must be performed for each work operation where necessary to assure quality. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel must be provided. Both inspection and process monitoring must be provided when control is inadequate without both.

(2) If mandatory inspection hold points, that require witnessing or inspecting by the applicant's designated representative and beyond which work may not proceed without the consent of its designated representative are required, the specific hold points must be indicated in appropriate documents.

(l) Test control. DOE shall establish a test program to assure that all testing required to demonstrate that structures, systems, and components ^{important to safety} will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents.

(1) The test program must include, as appropriate, proof tests prior to installation, preoperational tests, and operational tests during repository operation, of structures, systems, and components.

(2) Test procedures must include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions.

(3) Test results must be documented and evaluated to assure that test requirements have been satisfied.

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This subpart covers the storage of radioactive material by DOE in the Yucca Mountain repository and on the Yucca Mountain site. For the purposes of demonstrating compliance with this subpart, to the extent there may be any conflict with the requirements specified in this subpart and the requirements contained in subparts A-J of this regulation, including definitions, the requirements in this subpart shall take precedence.

§ 63.202 Definitions for subpart K.

Annual committed effective dose equivalent means the effective dose equivalent received by an individual in one year from radiation sources external to the individual plus the committed effective dose equivalent.

Committed effective dose equivalent means the effective dose equivalent received over a period of time (e.g., ³⁰30 years), as determined by NRC, by an individual from radionuclides internal to the individual following a one-year intake of those radionuclides. ✓

Effective dose equivalent means the sum of the products of the dose equivalent received by specified tissues following an exposure of, or an intake of radionuclides into, specified tissues of the body, multiplied by appropriate weighting factors.

General environment means everywhere outside the Yucca Mountain site, the Nellis Air Force Range, and the Nevada Test Site.

High-level radioactive waste means:

(1) The highly radioactive material resulting from the reprocessing of spent nuclear fuel, including liquid waste produced directly in reprocessing and any solid material derived from such liquid waste that contains fission products in sufficient concentrations; and

(2) Other highly radioactive material that the Commission, consistent with existing law, determines by rule requires permanent isolation.

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(c) does not exclude important parameters from assessments and analyses simply because they are difficult to precisely quantify to a high degree of confidence;

(d) focuses performance assessments and analyses ~~on~~ on the full range of defensible and reasonable parameter distributions rather than only upon extreme physical situations and parameter values.

§ 63.305 Required characteristics of the reference biosphere.

(a) Features, events, and processes that describe the reference biosphere must be consistent with present knowledge of the conditions in the region surrounding the Yucca Mountain site.

(b) DOE should not project changes in society, the biosphere (other than climate), human biology, or increases or decreases of human knowledge or technology. In all analyses done to demonstrate compliance with this part, DOE must assume that all of those factors remain constant as they are at the time of submission of the license application.

(c) DOE must vary factors related to the geology, hydrology, and climate based upon cautious, but reasonable assumptions ^{consistent with present knowledge of} ~~of the changes in these~~ factors that could affect the Yucca Mountain disposal system over the next 10,000 years.

(d) Biosphere pathways must be consistent with arid or semi-arid conditions.

POSTCLOSURE INDIVIDUAL PROTECTION STANDARD

§ 63.311 Individual protection standard after permanent closure.

DOE must demonstrate, using performance assessment, that there is a reasonable expectation that, for 10,000 years following disposal, the reasonably maximally exposed

AFFIRMATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER DICUS

SUBJECT: **SECY-01-0127 - DRAFT FINAL RULE - 10 CFR PART 63,
"DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN A
PROPOSED GEOLOGIC REPOSITORY AT YUCCA
MOUNTAIN, NEVADA**

Approved x Disapproved Abstain

Not Participating

COMMENTS:

See attached comments.

Greta Joy Dicus
SIGNATURE

August 28, 2001
DATE

Entered on "STARS" Yes x No

COMMENTS OF COMMISSIONER DICUS REGARDING SECY 01-0127

With respect to the number, range, and complexity of comments submitted to the NRC throughout the 10 CFR Part 63 rulemaking process, and for the extensive effort put forth in trying to resolve individual protection and ground water protection issues with the EPA, I commend staff for doing an outstanding job in finalizing the NRC's high-level waste regulatory requirements. I also would like to recognize the considerable progress that staff has made in maintaining and improving public outreach throughout the entire Yucca Mountain process.

As required by the Energy Policy Act of 1992, the NRC is in a position whereby it is legally bound to conform its final Yucca Mountain implementing regulations consistent with those of the EPA. Accordingly, I agree with the Chairman that staff has appropriately modified the NRC proposed rule to implement the EPA standards fully and thoughtfully. I also join the Chairman in recognition that the EPA's individual protection standard of 15 mrem/year and the separate 4 mrem/year ground-water resource protection standard (using EPA's maximum contaminant levels (MCLs)), departs significantly from the NRC proposed rule.

It is my personal view that EPA's introduction of new health-physics terminology, specifically, "annual Committed Effective Dose Equivalent," combined with its continued utilization of MCLs derived from outdated dosimetry and being non-uniform in their radionuclide risk application, are not based on sound science, are not internationally recognized, and do not provide greater protection levels than the NRC 25 mrem/year all-pathway protection standard. Although the NRC's proposed all-pathway dose limit of 25 mrem/year is not being applied to the Yucca Mountain site, I firmly believe that it remains scientifically sound and is fully protective of the public and the environment. I also remain supportive of its continued application in NRC regulated activities and facilities, such as, West Valley, where the EPA has formally recognized the 25 mrem/year all-pathway standard as being fully protective of the public and the environment. Nonetheless, since the NRC is legally required to conform its Yucca Mountain implementing regulations consistent with those of the EPA, I therefore approve, with comment, publication of the final rule in the Federal Register. I largely support the comments as provided in the Chairman's vote and offer the following specific viewpoints:

1. The final rule and Statement of Considerations (SOC) should be modified to reflect that the NRC will be utilizing the Total Effective Dose Equivalent (TEDE) dose methodology instead of the annual Committed Effective Dose Equivalent (CEDE) as proposed by the EPA. As a starting point, I recommend that staff utilize and optimally adopt the language provided in Footnote 1 of the Chairman's vote. To the extent appropriate, staff should also consider incorporating any successful harmonization efforts that the NRC and the EPA have concluded. I also recommend that the term "dose limit" be continually referenced throughout the rule language and SOC, as appropriate, in-lieu of referencing a specific dose methodology (i.e. TEDE). Much of the original language already addresses this issue, however, I prefer that it consistently and continually be referenced;
2. In Part 63 and consistent with the EPA's proposed and final 40 CFR Part 197, the NRC describes severability in terms of the individual protection standard and the ground-water

protection standard. Even though not addressed in either its proposed or final rule, the EPA asserts that severability also includes the human intrusion component as well. Premised upon the aforementioned, as well from additional discussions with the Office of General Counsel, I do not support including the human intrusion component as part of the NRC's implementing regulation or SOC. Since the EPA did not address or include human intrusion as being a severable component in its proposed or final regulations, I do not believe that staff should be placed in a position of having to introduce an issue that solely belongs to the EPA. I believe that if staff did address the issue at this time, we would have to consider whether a re-noticing of Part 63 would be warranted;

3. Since the EPA included the term "Very Unlikely" in both its proposed and final regulations with an assigned quantitative probability of 10^{-8} , I recommend that staff pursue the complimentary step of assigning a quantitative probability range to the term "Unlikely." This clarification will provide the next logical sequence of event probability cutoff ranges that I believe any potential licensee would need in order to make a compliance determination of an unlikely event. I agree with the Chairman that this effort should be undertaken as a separate rulemaking activity; and
4. I join the Chairman and Commissioner Merrifield in not seeking additional stakeholder input on the NRC's preliminary sufficiency comments regarding DOE's Yucca Mountain site characterization efforts.

A F F I R M A T I O N V O T E

R E S P O N S E S H E E T

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MCGAFFIGAN

SUBJECT: **SECY-01-0127 - DRAFT FINAL RULE - 10 CFR PART 63,
"DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN A
PROPOSED GEOLOGIC REPOSITORY AT YUCCA
MOUNTAIN, NEVADA**

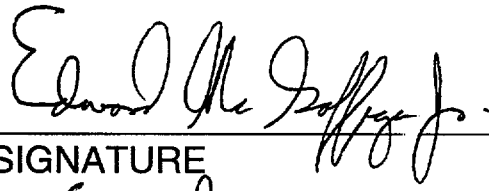
 w/comments & edits

Approved X Disapproved Abstain

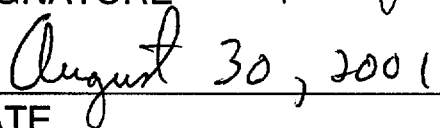
Not Participating

COMMENTS:

Please see attached comments and edits to the Federal Register.



SIGNATURE



DATE

Entered on "STARS" Yes X No

Commissioner McGaffigan's Comments on SECY-01-0127

I join my fellow Commissioners in commending the staff for their diligent efforts throughout the long process of completing the Part 63 rulemaking. I also join them in approving this final rule subject to some minor comments and edits which are discussed below.

My approval does not mean that I believe this is a good rule. By law, Section 801(b) of the Energy Policy Act of 1992, the Commission must amend its technical requirements and criteria to be consistent with the Environmental Protection Agency's (EPA's) standards promulgated under Section 801(a) of that Act. Therefore, we must by law incorporate a nonsensical ground water protection standard into our rule and we have done so in §§63.331 and 63.332.

Why is this EPA groundwater standard nonsensical? The standard calls for a limit of 4 millirem per year to the whole body or any organ for beta and photon emitting radionuclides from the groundwater pathway, based on drinking 2 liters of water per day from the representative volume of water. This is a standard rooted in outdated science which EPA had proposed to change in a 1991 proposed rule to 4 millirem effective dose equivalent¹. Effective dose equivalent is the modern internationally accepted approach to compute the overall effect of a dose on an individual. It takes into account the latest scientific understanding of the variable effect of radiation on different organs. It results in a consistent approach to risk. Unfortunately, in its December 7, 2000 final rule EPA decided against good science, abandoned its 1991 proposal, and instead maintained the existing rule. EPA vaguely promised a "near future review of the beta particle and photon radioactivity maximum contaminant level (MCL)," but implied that it believes that Section 1412(b)(9) of the Safe Drinking Water Act may constrain it from adopting a uniform risk MCL based on current science.

The sad result is that under the EPA Yucca Mountain groundwater standard, the de facto standard for the potential repository is the most broken MCL for a long-lived radionuclide, namely the 1 picocurie per liter MCL for iodine-129 which was chosen based on the radio sensitivity of the thyroid gland. This MCL corresponds to 200 microrem per year effective dose equivalent.² EPA's Federal Guidance Report 13, published in September 1999, places the annual risk of a cancer fatality as a result of the iodine-129 MCL at about one chance in 100,000,000³. This is an absurd place to be regulating. What other activities in which we engage on a daily basis expose us to this sort of dose? I live in a brick home. I have measured the gamma radiation in my

¹The World Health Organization in its 1993 guidelines for drinking water quality had recommended a reference level of 10 millirem per year effective dose equivalent for beta and photon emitters and stated "Below this reference level of dose, the drinking water is acceptable for human consumption and action to reduce the radioactivity is not necessary."

²EPA proposed an iodine-129 MCL of 21 picocuries per liter in its 1991 proposed rule.

³It should be noted that this is based on the linear no-threshold hypothesis for extrapolating risk. When we extrapolate to 200 microrem per year effective dose equivalent, we are many orders of magnitude away from where there is real data on cancer risks (largely from the Hiroshima and Nagasaki bomb follow-up studies) and it is quite possible there is no adverse health effect at all at these low doses and low dose rates.

home at 8 - 15 microrem per hour. In less than 24 hours in my home I will receive more than 200 microrem. My son worked as a U.S. Senate page this past spring. I have measured the gamma radiation in the Senate side of the Capitol in the 15 - 30 microrem per hour range. Each working day he received about the Yucca Mountain standard. A one-way non-stop flight from Washington to Los Angeles at 35,000 feet results in an effective dose from cosmic radiation of 1720⁴ microrem, eight and a half times the EPA standard. If I eat a banana a day (which as a long distance runner I do), I will get about 2,000 microrem per year from the naturally occurring radioactive isotope potassium-40 in the banana, about 10 times the EPA standard. The EPA standard for radon in homes, 4 picocuries per liter of air⁵, translates to doses as high as 600,000 microrem per year, 3,000 times the EPA Yucca Mountain groundwater standard. A typical abdominal Computerized Tomography scan for medical diagnostic purposes results in a dose on the order of 2,500,000 microrem, 12,500 times the EPA Yucca Mountain groundwater standard. I could go on and on.

Both the Nuclear Regulatory Commission (NRC) and the National Academy of Sciences have strongly argued against the EPA groundwater standard. Section 801(a) of the Energy Policy Act of 1992 gave EPA authority to set generally applicable standards for the Yucca Mountain site. In doing so it states: "Such standards shall prescribe the maximum annual effective dose equivalent (underline added) to individual members of the public from releases to the accessible environment from radioactive material stored or disposed of in the repository." EPA met the law when it prescribed the 15 millirem per year effective dose equivalent all-pathways individual protection standard. It went beyond the law in prescribing an outdated and nonsensical groundwater standard. It did so as a matter of policy, a policy that has never gone through rulemaking, that EPA will protect potential sources of groundwater the same way it protects water at the tap. NRC questioned the cost/benefit of this policy applied to the Yucca Mountain standard. Yet nowhere in the EPA rulemaking file can I find a cost/benefit justification for this groundwater standard. EPA also argued for the standard based on consistency with its regulations for the Waste Isolation Pilot Plant (WIPP) in New Mexico. But as NRC pointed out in its comments, the groundwater issue simply doesn't arise at WIPP because the groundwater there is not potable.

EPA wisely made its individual protection standard and its groundwater standard severable in its final rule. We are doing the same as we incorporate EPA's standards. I hope that the Courts will strike down the groundwater standard. While I would have preferred a 25 millirem per year effective dose equivalent individual protection standard and believe that it would have been fully protective of public health and safety, the EPA's 15 millirem per year effective dose equivalent individual protection standard is not unreasonable. Its 200 microrem per year groundwater standard can not be defended.

⁴Nuclear News, January 2000 edition, page 36.

⁵This is the level above which EPA recommends that mitigative action be taken. It is not enforced and is up to individual homeowners to take the initiative to test and, if necessary, remediate their homes. I tested my home in the mid-1980s and happily it was well below the EPA action level.

Other Comments:

Total Effective Dose Equivalent:

After consideration of the calculational differences between the terms “total effective dose equivalent (TEDE)” used routinely by NRC and “annual committed effective dose equivalent (Annual CEDE)” used by EPA in 40 CFR Part 197, I agree with my fellow Commissioners to support the use of TEDE in Part 63. In this application, the two terms are essentially equivalent and it is my understanding EPA agrees. The staff should add a brief discussion in the FRN describing the essential equivalence of the two terms and the basis for the Commission’s decision to use TEDE, and make conforming changes throughout the FRN.

Human Intrusion:

Since issuance of the Part 63 proposed rule for comment, my thinking has significantly evolved on this issue based on public comment and the approach used by EPA in its final rule. The proposed rule contained a “stylized” calculation that prescribed the timing of the intrusion (i.e., 100 years after permanent closure), the repository barriers affected by the intrusion and the relevant exposure pathway. I agree with the public comments that there is no reason to believe that human intrusion could occur at Yucca Mountain as early as 100 years after closure. Active institutional controls, which by law (Section 801(c) of the Energy Policy Act of 1992 incorporated in our rule at § 63.51(a)(3)(iii)) must be maintained indefinitely, will likely be in place much longer than 100 years. Moreover, the likelihood of drilling into Yucca Mountain for water or other resources, should these active institutional controls somehow fail, presumably because of an unforeseen catastrophe that ends our civilization, is very small. In contrast, the draft final amendments to § 63.321 (human intrusion standard) and § 63.322 (human intrusion scenario), which incorporate EPA’s approach, are an improvement over the proposed rule since they are more performance-based, providing DOE flexibility to determine and justify (subject to NRC review) its selection of the time of the intrusion event based on the condition of the waste package subject to an annual individual dose limit of 15 millirem per year effective dose equivalent.

Multiple Barriers and Defense in Depth:

I fully support the final rule’s approach to multiple barriers and defense in depth and believe that § 63.115 is entirely consistent with the statutory mandate in Section 121(b)(1)(B) of the Nuclear Waste Policy Act that our rule “shall provide for the use of a system of multiple barriers in the design of the repository.”

Reasonable Expectation versus Reasonable Assurance

This is an area where EPA made a contribution to the overall standard setting effort. Our proposed rule used the term “reasonable assurance,” partly because we had always used it, but the proposed § 63.101 really was describing “reasonable expectation.” The final rule is an improvement.

Severability of Standards

Another issue which has arisen during the review of the final rule is the severability of certain provisions in the EPA and NRC rules, i.e., individual and ground water protection standards. Based on the information before us, I agree with the staff that the plain English of the EPA rule applies the severability provision to the individual and ground water protection standards only and does not include the human intrusion standard.

Separate Rulemaking on Probability of Unlikely Events or Processes

I agree with my fellow Commissioners that a separate rulemaking should be initiated on an expedited basis to establish the annual level of probability of occurrence constitutes an unlikely event or process.

Consistency in Definitions

I agree with Chairman Meserve that the definitions of “high-level waste” and “ground water” are problematic, in that the definition of HLW needs to be consistent with the definition in the Nuclear Waste Policy Act of 1982, as amended, and the definitions of ground water are internally inconsistent. These definitions need to be corrected as suggested by the Chairman.

Additional General Comments:

I fully agree with my fellow Commissioners regarding their concerns on § 63.16(d) and firmly believe that the Commission is in a position to make an informed decision on the sufficiency of the Department of Energy’s site characterization efforts to date without additional input from stakeholders. Therefore, I would not support a decision to solicit additional stakeholder input on the Commission’s sufficiency comments to DOE.

Also, after promulgation of the Part 63 final rule, I encourage the staff to promptly publish a Federal Register notice to close out action on the petition for rulemaking originally submitted in 1985 by the States of Nevada and Minnesota and inform the affected States of this action.

Finally, suggested edits to the Federal Register notice are indicated on the attached pages.

However, the EPA standards do not ^{specify} ~~specific~~ a frequency for unlikely features, events, and processes, and acknowledges a value is to be specified by NRC (66 FR 32135). NRC fully supports excluding unlikely features, events, and processes from analyses for estimating compliance with the standards for human intrusion and ground-water protection. While we have provided no specific quantitative value for determining when exclusion of unlikely features, events, and processes is appropriate, the final regulations allow DOE to exclude unlikely features, events, and processes from the specified analyses with the prior approval of the Commission. The Commission recognizes that specification of a probability limit for unlikely features, events, and processes, as is done for "very" unlikely features, events, and processes, would be a more direct approach. Although the Commission considers a frequency for unlikely features, events, and processes would fall somewhere between 10^{-8} to 10^{-4} per year, the Commission has decided not to specify a value in the regulations at this time. The Commission considers this approach to be consistent with the intent of EPA's final standards and may revisit the question of specifying a numerical value by rulemaking in the future.

TOTAL EFFECTIVE DOSE EQUIVALENT

The EPA standards use the term "annual committed effective dose equivalent" (annual CEDE) to denote the total dose resulting from internal and external exposure to radiation resulting from a single year's exposure. A distinction is made between internal and external doses, because internal exposures (e.g., ingestion and inhalation of radionuclides) continue as long as the radioactive material remains within the body, and disproportionally affect internal organs, depending on where a particular radionuclide is retained in the body. Thus, internal exposure is determined by calculating a CEDE that takes into account the fact that internally

deposited nuclides may deposit radiation non-uniformly in the body over long and variable time frames. External exposure results from an individual's proximity to a radiation source present outside the body and does not require consideration of radionuclides retained in the body. The total dose is represented as an "annual CEDE" that is the summation of the internal and the external exposures.

The NRC and EPA approaches for estimating a total exposure to an individual are based on the summation of the internal exposure (determined using a CEDE approach) and the external exposure. However, EPA and NRC use different terminology in regulations and standards to describe this total exposure. EPA uses the term "annual CEDE" whereas NRC uses "total effective dose equivalent in a year" (TEDE in a year) to define the same concept. Specifically, NRC defines terms for dose extensively in 10 CFR Part 20, and uses terms consistent with traditional health physics definitions. By those definitions, Total Effective Dose Equivalent, or TEDE, is the sum of the dose from external exposure and the CEDE (for internal exposures).

Part 63 has adopted EPA's term "annual CEDE" for purposes of compliance with Subparts K and L. However, the Commission is aware that adopting CEDE in one portion of Part 63 and TEDE in another part of the Commission's regulations could be a source of confusion. Further, the dose estimation will be the same regardless of which agency's terminology is used. Therefore, the Commission would be inclined to accept a DOE demonstration in terms of either TEDE in a year or annual CEDE to meet the dose limits of Subparts K and L. [note: separate requirements for ground-water protection are still required to evaluate dose to the whole body and the organs for beta and photon emitting radionuclides].

REQUIREMENTS FOR ENVIRONMENTAL IMPACT STATEMENT

EPA's standards require DOE to estimate peak dose under the evaluations for individual protection and human intrusion. The results of these evaluations are to be included in DOE's environmental impact statement (EIS). The Commission has modified Part 63 to include the provision that DOE must include peak dose estimates in its EIS, but notes that there is no standard that must be met with respect to these peak dose calculations, and that there is no finding that the NRC must make with respect to these peak dose calculations nor may they be the subject of litigation in any NRC licensing proceedings for a repository at Yucca Mountain. However, DOE still must carry out its responsibilities under the National Environmental Policy Act in accordance with the final EPA standards.

IMPORTANT TO WASTE ISOLATION

Proposed Part 63 defined "important to waste isolation" in the context of meeting the individual dose limit for the postclosure period of the repository (i.e., disposal). This use of the term is important in defining the scope of the requirements for: DOE's quality assurance program (specified at Subpart G); multiple barriers (specified at 10 CFR 63.113); performance confirmation (specified at Subpart F); and changes, tests, and experiments (specified at 10 CFR 63.44). The Commission has expanded the definition of the term, "important to waste isolation" to include both the dose limit and the separate ground-water protection limits contained in the EPA standards.

III. Public Comments and Responses

Staff Paper says "160"

? x In preparing the final rule, the NRC staff carefully reviewed and considered more than 700 discrete comments enclosed in about 100 individual letters received during the public comment period. The staff also identified and evaluated an additional 193 comments made at public meetings. To simplify the analysis, the NRC staff grouped all written and oral comments on the rule into the following six major topic areas:

- 1) Regulatory Process and Licensing Process;
- 2) Requirements for the Pre-closure Period;
- 3) Requirements for the Post-closure Period;
- 4) General Requirements;
- 5) Selected Topics; and
- 6) Beyond the Scope of This Rulemaking.

1 Regulatory Process and Licensing Process

1.1 Promulgation in Advance of EPA Standards

Issue 1: Is NRC's action in promulgating Part 63 in advance of EPA standards beyond the scope of its authority?

Comment. Many of those who commented on the NRC's proposed Part 63 expressed concern that NRC was "usurping" EPA's authority by declaring its own standards and technical requirements in advance of EPA's issuance of final standards. For example, the State of Nevada pointed out the EnPA does not mandate a new Commission rule specific to Yucca Mountain to replace its general rule for licensing geologic repositories. It only requires modification of NRC's technical requirements and criteria, as necessary, to be consistent with

to accomplish these objectives is preferable to modifying its generic requirements, given that EnPA and NAS laid out a fundamentally different approach for Yucca Mountain than was contemplated when the generic criteria were promulgated. Specifically, EnPA and NAS outlined an approach that would require the performance of a Yucca Mountain repository to comply with health-based standards established in consideration of risk to individuals in a hypothetical group. The law also stated that the new health-based standards were to be the only quantitative standards for the post-closure performance of the repository. This approach departs from the approach taken in the existing generic criteria which rely on compliance with cumulative release limits and separate, quantitative, subsystem performance objectives. Further, the Commission's current approach is consistent with EPA standards for Yucca Mountain. Therefore, after carefully considering the public comments, the Commission remains of the view that it is best to develop site-specific regulations -- regulations that: reflect an improved scientific understanding of the site; are based on state-of-the-art analyses; are consistent with the Commission's philosophy to implement risk informed regulation; and that implement the separate, site-specific standards that EPA has issued for Yucca Mountain.

Commenters correctly pointed out that there are significant differences between Part 60 and Part 63. In the Commission's view, the Part 63 regulations do not lessen DOE's responsibility in any way to safely site, design, and operate the proposed repository. Much has been learned regarding the expected performance of geologic repositories in general (Nuclear Energy Agency, *Lessons Learnt from Ten Performance Assessment Studies*, Paris, France, NEA/OECD Working Group on Integrated Performance Assessments for Geologic Repositories, 1997), and a potential Yucca Mountain repository in particular over the nearly two decades since Part 60 was written. Part 63 reflects and incorporates much of this new information. The risk-informed, performance-based approach used to develop the rule (see SECY-97-300, "Proposed

Strategy for Development of Regulations Governing Disposal of High-Level Radioactive Wastes in a Proposed Repository at Yucca Mountain, U.S. NRC, December 24, 1997) eliminates arbitrary or prescriptive siting and design criteria, as well as detailed requirements such as quantitative subsystem performance objectives. That being said, however, Part 63 still requires DOE to demonstrate reliance on multiple barriers and defense in depth, preservation of the retrieval option, implementation of a performance confirmation program, transparency in decision making, and application of rigorous quality assurance (QA). Moreover, as a result of public comments, other provisions have been added to Part 63 to ensure the adequacy and sufficiency of DOE's compliance demonstrations. (See Multiple Barriers and Defense in Depth for additional discussion on quantitative subsystem requirements.)

1.2 Differences Between Part 63 and EPA Standards for WIPP

Issue: Why is there a difference between the performance objectives in NRC's proposed 10 CFR Part 63 for Yucca Mountain and EPA's 40 CFR Part 191 standards used to certify the Waste Isolation Pilot Project (WIPP)?

Comment. Many commenters expressed concern that NRC's proposed regulations for Yucca Mountain provided less protection than EPA's standards for WIPP. They regarded NRC's proposed regulations as less stringent than the standards for WIPP. Many cited the absence of separate criteria for protection of ground water in NRC's proposed regulation as evidence that the WIPP standards, which include separate requirements for protection of ground water, are more restrictive. Commenters also cited the differences in the individual protection limits [0.15 mSv/year (15 mrem/year) for WIPP compared to 0.25 mSv/year (25 mrem/year) limit for Yucca Mountain], and the compliance location (5 km for WIPP compared to

practices and is acceptable to NRC. DOE also suggested that the potential dose arising from the occurrence of each Category 2 DBE [event sequence] should be estimated separately (i.e., not be aggregated). The Commission agrees that each Category 2 event sequence is to be evaluated individually, as this approach is consistent with historical practices. Also, analyzing each event sequence separately provides a high degree of transparency in the analysis, thus allowing NRC to evaluate the postulated events, the associated event sequences, and the engineered components that affect the likelihood and magnitude of potential releases of radioactive material. The Commission has revised the rule at § 63.111^{63.111}(b)(1) and (2) to clarify that dose estimates for Category 1 event sequences are to be aggregated, but those of Category 2 event sequences are to be analyzed and documented individually. X

DOE also suggested that, for Category 2 DBEs [event sequences], dose calculations for ingestion are not necessary. The Commission sees no compelling logic for the specific pathways for dose calculations being different for Category 1 and Category 2 event sequences. Dose should be calculated considering all pathways relevant to an event sequence. Consistent with the Commission requirements elsewhere, the DOE must consider all pathways in demonstrating compliance with § 63.111. The risk-informed regulation anticipates that DOE will present in its license application the magnitude of, and the technical basis for, the dose contribution of various pathways, including the technical bases for eliminating any pathway.

Issue 4: What precedents, if any, do NRC regulatory guides, developed for other applications such as nuclear power plants, have for use in developing DBEs [event sequences] for a potential repository at Yucca Mountain?

Comment. DOE asked for clarification about the role of precedents in other regulatory guides (e.g., consideration of earthquakes, aircraft crashes, tornadoes, and flooding) in

determining what should be considered in the development of DBEs [event sequences] (especially for Category 2). DOE also commented that development of credible natural events, for Category 2 DBEs [event sequences], would require only following applicable regulatory precedents and considering severe natural phenomena that have been historically reported for the site and geologic setting.

Response. The applicability of regulatory guidance developed for facilities other than a high level waste repository will need to be considered on a case-by-case basis for applicability to high level waste disposal at Yucca Mountain. For the guidance to be appropriate, it should be generally applicable to nuclear facilities with comparable or higher risks to workers and the public than the potential repository at the Yucca Mountain site (see discussion under Issue 2).

Issue 5: What is the status of NRC's provisional acceptance of DOE's Topical Report on Seismic Design for Yucca Mountain with respect to event sequences in Part 63?

Comment. DOE inquired about the status of NRC's provisional acceptance of DOE's Topical Report on Seismic Design for Yucca Mountain with respect to event sequences in Part 63.

Response. DOE's Topical Reports 1 and 2 on Seismic Design for Yucca Mountain were provisionally accepted prior to NRC's issuance of proposed requirements at Part 63. The applicability of DOE's seismic design methodology will be reviewed after final Part 63 requirements are in place, and DOE has completed Topical Report 3.

Issue 6: Should there be an explicit requirement for an analysis of the effects of any plans for use of the air space above the GROA?

performance confirmation plan that focuses on those natural and engineered systems and components important to repository performance and operation. The requirements allow DOE the flexibility to develop a focused and effective performance confirmation program. An alternative approach would be to prescribe in detail the specifics and limits of that program. The Commission does not want to limit DOE's options regarding testing methodologies and has chosen not to follow that approach. Note, however, that NRC will evaluate the adequacy of the performance confirmation program in the course of its review of the license application.

Issue 3: Is the performance confirmation data required to be used in the updating of the performance assessment?

Comment. EPA recommended that performance confirmation data should be explicitly identified as information to be included in the update of the performance assessment required at the time of the amendment for permanent closure [§ 63.51(a)(1)].

Response. The Commission agrees with the commenter and has modified the rule accordingly.

2.4 Pre-closure Operations Activities

Issue: Should the proposed rule specify environmental monitoring requirements for regulating releases from the pre-closure operational activities?

Comment. The EPA commented that requirements for environmental monitoring during the operational phase of the repository were not in the proposed rule and there were no methods stated in the rule for enforcement of the pre-closure requirements.

Response. The Commission considers that proposed Part 63 has sufficient requirements for environmental monitoring during the operational phase of the repository and is not revising the rule ^{on issues} ~~in this matter~~. The Commission has included environmental monitoring requirements for radioactive releases in Part 63. Sections 63.111 and 63.112 require DOE to account for, design against, and monitor any potential event sequences that could lead to radioactive releases. As part of the PSA (§ 63.112), for example, DOE is to describe its design and operating procedures for monitoring and controlling radioactive releases. Consistent with its National Environmental Policy Act (NEPA) responsibilities, DOE has already described its plans and procedures for the monitoring (and mitigation) of environmental impacts due to the operation of the geologic repository, including radioactive releases, in its DEIS for Yucca Mountain.

Regarding the comment on the lack of enforcement methods in the rule, Subpart J of Part 63 addresses enforcement at a level of detail that the Commission has typically used in all its regulations. Specific policy and procedure issues for enforcement activities are described in NRC's "General Statement of Policy and Procedure for NRC Enforcement Actions," the NRC enforcement manual, and supplemental guidance. The Commission believes this is an appropriate approach for its regulations and will retain the current language as in the proposed rule under Subpart J. The Commission plans to develop specific changes to the enforcement policy and procedures as part of development of inspection and oversight plans for implementation of Part 63.

2.5 Emergency Planning Criteria

Issue 1: If local emergency first-responder capabilities and emergency medical services are not sufficient for reacting to nuclear accidents at the geologic repository, will NRC require DOE to enhance existing local capabilities in the Yucca Mountain region?

Comment. Commenters expressed concern that current local emergency and medical services are not adequate to respond to potential nuclear accidents at a geologic repository at Yucca Mountain. Accordingly, it was suggested that NRC include, as a license condition to operate the repository, a requirement that DOE enhance local capabilities for responding to potential nuclear accidents.

Response. Part 63 (Subpart I) requires DOE to submit an emergency plan for coping with radiological accidents. NRC's review of DOE's emergency plan will evaluate the adequacy of the plan including such things as the capability to respond to accidents and medical assistance for treatment of radiological injuries. Where DOE's emergency plan is found to be inadequate, the NRC, if necessary, can impose license conditions that require DOE to correct any deficiencies. (See also response to Issue 3 below.)

Additionally, U.S. Federal Emergency Management Agency (FEMA) regulations, as well as DOE orders, require that DOE have an emergency response capability that is adequate to meet anticipated accidents, including potential radiological accidents. DOE is responsible for ensuring that the emergency treatment capability exists and is documented in its emergency plan, which is subject to NRC review in accordance with § 63.161.

Issue 2: Will DOE's emergency plans be sufficiently comprehensive to include such scenarios as emergency evacuation procedures and responses to terrorist activity?

Comment. Some commenters were concerned whether DOE would have adequate, effective, and sufficiently comprehensive plans and procedures to address most, if not all, potential accidents, incidents, and/or contingencies.

Response. The rule requires DOE to have plans to cope with radiological accidents (emergency planning at § 63.161) and provide for physical protection [§ 63.21(b)(3)]. These plans are required to address a number of criteria to ensure that DOE is prepared to respond, both on site and off site, to accidents, and that DOE has the capability to detect and respond to unauthorized access and activities that could threaten the physical protection of HLW. As noted in the response above, NRC and FEMA regulations, as well as DOE orders, require that DOE have adequate plans and procedures in place to address any potential accidents and incidents. DOE's emergency plan and physical protection plan are subject to NRC review. The Commission believes that the requirements for DOE's plans for emergencies and physical protection expressed in the proposed Part 63 are appropriate and ^{has} ~~will~~ ^{ed} retain them in the final rule.

Section 63.161 requires DOE to develop an emergency plan based on the criteria of § 72.32 [i.e., criteria provided for an Emergency Plan for an Independent Spent Fuel Storage Installation (ISFSI)]. The required Emergency Plan includes: identification of each type of accident, description of the means of mitigating the consequences of each type of accident; prompt notification of offsite response organizations; and adequate methods, systems, and equipment for assessing and monitoring actual or potential consequences of a radiological emergency condition. If particular types of accidents require evacuation procedures to ensure the protection of public health and safety, they will be included in the Emergency Plan.

Section 63.21(b)(3) requires DOE to submit a detailed plan to provide physical protection of HLW in accordance with § 73.51 (requirements for physical protection of stored spent nuclear fuel and HLW). The requirements for physical protection include: (1) capabilities to detect and

assess unauthorized access or activities and protect against loss of control of the facility; (2) limiting access to HLW by means of two physical barriers; (3) providing continual surveillance of the protected area in addition to protection by an active intrusion alarm; and (4) providing a primary alarm station located within the protected area and have bullet-resisting walls, doors, ceiling, and floor. These requirements provide high assurance that physical protection of the repository includes appropriate measures to prevent and respond to unauthorized access and activities, including the potential for armed intruders (e.g., terrorist activity).

Issue 3: Will Federal funding be available to upgrade emergency first-responders and emergency medical services so as to allow local communities to be better prepared to respond to potential transportation accidents?

Comment. Counties in the Yucca Mountain region expressed concern with their ability to respond to medical emergencies resulting from a transportation accident involving nuclear waste. Local communities suggested that DOE be required to enhance local emergency capabilities for responding to transportation accidents.

Response. Section 180(c) of the NWPA requires DOE to provide technical assistance and funding for training State and local governments and Tribes for safe routine transportation and emergency response. However, NRC's responsibility for oversight and review of DOE's emergency plans (see discussion under Issues 1 and 2) does not include responsibility for how DOE provides for technical assistance and funding. Additionally, under NEPA, the potential for (environmental) impacts due to transportation, including accidents, is the responsibility of DOE to assess and mitigate.

3 Requirements for the Post-closure Period

3.1 Post-closure Safety Assessment

Issue 1: Can performance assessments be relied on as the sole quantitative technique for evaluating compliance with post-closure safety requirements?

Comment. DOE and NEI supported the risk-informed, performance-based approach. Additionally, NEI supported requirements in proposed Part 63 intended to ensure that DOE conducts and documents a high-quality performance assessment [e.g., features, events, and processes (FEPs) be described; relevant conceptual models be considered] and NEI also expressed a need for the NRC to effectively and clearly articulate this approach in future regulatory efforts. However, other commenters indicated that, although performance assessment is a highly informative methodology, its capability to model complex, coupled geologic systems over extended time periods has yet to be demonstrated. Confidence in performance assessments could be improved through testing on actual geologic systems and conducting suitable, long-term studies.

Response. Although repository post-closure performance is evaluated with respect to a single performance measure, the NRC considers a broad range of information in arriving at a licensing decision. In the case of the proposed repository at Yucca Mountain, Part 63 contains a number of requirements (e.g., qualitative requirements for data and other information, the consideration and treatment of uncertainties, the demonstration of multiple barriers, performance confirmation program, and QA program) designed to increase confidence that the post-closure performance objective is satisfied. The Commission will rely on the performance assessment as well as DOE's compliance with these other requirements in making a decision, if DOE submits a license application for disposal of HLW at Yucca Mountain. The Commission believes the approach for performance assessment in the proposed rule is appropriate and is retained in the

final rule. However, requirements for QA, multiple barriers, and performance confirmation have been revised to clarify the Commission's intent for these requirements (see discussion under Quality Assurance, Multiple Barriers and Defense in Depth, and Performance Confirmation for more details).

The Commission believes that there have been significant advances in, and experience with, risk assessment in the past 20 years (see Commission's white paper on Risk-Informed and Performance-Based Regulation, March 1999). The Commission continues to believe that a performance assessment, developed with sufficient credibility, is the best means to provide useful information to the Commission for making an informed, reasonable licensing decision. The Commission recognizes, however, the uncertainties inherent in evaluating a first-of-a-kind facility like the repository and in estimating system performance over very long time periods (i.e., 10,000 years). Thus, proposed Part 63 contained requirements to ensure: ^{that} (1) uncertainties inherent in any performance assessment are thoroughly articulated and analyzed or addressed; (2) DOE's performance assessment is tested (corroborated) to the extent practicable; and (3) there are additional bases, beyond the performance assessment, that provide confidence that the post-closure performance objectives will be met. For example:

1. Requirements for addressing uncertainty in performance assessment.

Section 63.114 provides a number of requirements for DOE's performance assessment to thoroughly address uncertainty. Part 63 requires consideration of uncertainties in DOE's representation of the repository [uncertainty and variability in parameter values must be taken into account - § 63.114(b)] and the events that can happen during the compliance period [consideration of potentially disruptive events with a probability of occurrence as low as one chance in 10,000 of occurring over 10,000 years - § 63.114(d)] to be directly included in the

quantitative estimate of performance. Additionally, DOE is required to provide additional assurances that uncertainty in the information (e.g., evaluation of site characterization data) used to develop the performance assessment have been evaluated by consideration of alternative conceptual models of features and processes that are consistent with available data and current scientific understanding [§ 63.114(c)]; and the basis for inclusion or exclusion of FEPs that would have a significant effect on performance [§ 63.114(e) and (f)]. (See discussion under Issue 2 for further details on uncertainty in performance assessment.)

2. DOE's performance assessment is tested (corroborated) to the extent practicable.

DOE must test or corroborate, to the extent practicable, the confidence in (validity of) the performance assessment models. Part 63 requires DOE to provide the technical basis for the models used in the performance assessment [§ 63.114(g)]. Approaches for providing the technical basis would include comparisons of these models with information relevant to the conditions of geologic disposal and time periods of the assessment (e.g., results from detailed process-level models, field investigations, and natural analogs). Additionally, a performance confirmation program is required (Part 63, Subpart F) to confirm that the behavior of the barriers of the repository system is consistent with what has been assumed in the performance assessment (see discussion under Performance Confirmation for more details).

3. Basis for confidence that the post-closure performance objectives will be met.

As a basis for confidence that the post-closure performance objectives will be met, the Commission plans to rely on requirements in addition to that for the performance assessment. Specifically, Part 63 requires a multiple barrier approach for the repository, and a QA program. A requirement that multiple barriers make up the repository system ensures that repository

standard. The commenter recommended that plain English should be used to document the performance assessment to improve overall understanding of the risks.

Response. The Commission agrees that DOE's performance assessment needs to be clearly documented. Part 63 provides the requirements for DOE's performance assessment at §63.114 and requirements for the content of the application at § 63.21. These requirements provide a general description of the types of information that need to be included in the license application but do not prescribe specific details for the format of the documentation. The Commission believes it is inappropriate and unnecessary to prescribe, in the regulations, further details for DOE's documentation. The performance assessment is DOE's analysis, and DOE needs flexibility in deciding ~~on~~ how best to document its analysis. However, the NRC staff is developing a YMRP to provide guidance to DOE on approaches for documenting performance assessment results that are both transparent and traceable. The Commission agrees with improving overall understanding of performance assessment through better documentation and will interact with the public and DOE to improve the YMRP in this important area.

Issue 5: Why does NRC require DOE to evaluate alternative designs?

Comment. DOE questioned the regulatory basis of § 63.21(c)(7) that requires DOE to evaluate alternative designs. DOE believes evaluation of alternative designs goes beyond typical licensing practice by implying a need for DOE to justify selection of one design over another. DOE suggested they should be allowed to select the design that best suits their purposes consistent with the approach given other NRC regulated activities at § 50.109(a)(7). Another commenter suggested that the consideration of alternative designs be limited to present-day technology.

Response. The Commission agrees with the comments and has removed this requirement from the regulations. The NRC review should focus on the safety aspects of DOE's proposed approach. DOE should only be required to propose alternatives from its proposed approach in areas where the NRC review determines DOE's approach is deficient.

When developing proposed Part 63, the staff adopted this requirement from 10 CFR Part 60, the existing generic NRC HLW disposal regulation, which contains a similar requirement in 10 CFR 60.21 (c)(1)(ii)(D). At the time of the issuance of Part 60, DOE objected to this specific requirement with basically the same argument presented for Part 63. In the ~~Statements~~ of Consideration^(c) for Part 60 (published in Federal Register on June 21, 1983), the Commission justified the requirement by stating "If the Commission finds, on the basis of its review, that the adoption of some alternative design feature would significantly increase its confidence that the performance objectives would be satisfied, and that the costs of such an approach are commensurate with the benefits, it should not hesitate to insist that the alternative be adopted."

The decision to require DOE to submit alternatives for certain site design features was a discretionary action on the part of the Commission as nothing (in either the Atomic Energy Act of 1954, as amended, or the Nuclear Waste Policy Act of 1982, as amended) required the Commission to obtain information on alternative designs at the site level. At the time Part 60 was initially published (1983), the Commission implemented an appropriate regulatory framework for a generic program facing many uncertainties. Multiple sites with very different geological settings were under consideration. The NRC's generic HLW regulations had to address the resolution of a large number of technical issues in the relative short licensing review period established by the Nuclear Waste Policy Act of 1982. With all the uncertainties in the program, the Commission

believed it was important to require design alternatives be submitted with the application to increase the probability of NRC approval of the license application within the three year schedule mandated by Congress.

The Commission has revisited the decision to require submission of alternative designs. Specifically, the Commission no longer believes this information should be submitted with a license application and, accordingly, has removed this requirement. To protect public health and safety and the common defense and security, which is the NRC's mandate under the Atomic Energy Act of 1954 as amended, the Commission will closely scrutinize the design proposed by DOE. Consistent with this mandate, the new Part 63 is designed to be a risk-informed, performance-based regulation which establishes overall repository performance objectives. DOE must demonstrate that the repository meets the performance objectives. The NRC review is an audit of the DOE demonstration to determine if we agree that the performance objectives have been met. If the NRC believes that the site does not meet the performance objectives within uncertainties addressed in the analysis, then it is DOE's responsibility to either defend its current design or propose an alternative design that can meet the NRC acceptance criteria.

3.2 Individual Dose Limit

Issue 1: How is the protection of future generations considered as part of setting the dose limit?

Comment. A number of commenters expressed concern that the dose limit specified in the proposed rule provided inadequate protection for future generations. Commenters suggested that (1) selection of the dose limit should consider the unpredictability of the future, particularly

where and how an individual would be exposed, and (2) the dose limit should reflect impacts from either future energy development or past releases on the local community, such as ground-water releases from the NTS or the Beatty Low-Level Waste facility, in developing the standard.

Response. The purpose of the post-closure dose limit and the performance assessment is to ensure that future generations will be adequately protected. EPA has established, and the Commission ^{has} will incorporate ^d a ^{individual} dose limit of 0.15 mSv/year (15 mrem/year). The Commission is confident that this limit is fully protective and that it provides an added margin of safety beyond what is necessary to ensure public health and safety. The Commission has long held that ⁿ a ^{individual} dose limit of 0.25 mSv/year (25 mrem/year) ^{TEDE} is (1) a reasonable and appropriate level of protection for future generations, (2) within the range of dose limits used for current sources of public exposure, and (3) accounts for the possibility of dose from other sources.

In judging the adequacy of a dose limit for waste management and other related activities, NRC considers recommendations from the International Commission on Radiological Protection (ICRP), National Council on Radiation Protection and Measurements (NCRP), EPA, and International Atomic Energy Agency (IAEA). The ICRP's and NCRP's recommendations are developed by recognized experts in the fields of radiation protection and health effects. The NCRP is a nonprofit corporation chartered by the U.S. Congress to develop and disseminate information and recommendations about radiation protection and to cooperate with the ICRP and other national and international organizations with regard to these recommendations. The ICRP is an international panel of radiation experts from all fields that provides estimates of radiation risk and recommendations on radiation protection and has continued to update and revise its risk estimates and radiation protection recommendations since its inception in 1928. In its deliberations, ICRP maintains relationships with United Nations health and labor organizations.

The IAEA is a United Nations agency involved in assisting member states to establish consistent radiation protection standards. In 1995, the IAEA identified a number of principles with the express purpose of giving a common basis for the development of more detailed standards and a basis for national waste management programs [The Principles of Radioactive Waste Management, IAEA Safety Series No.111-F, International Atomic Energy Agency, Vienna (1995)]. Two of the principles are:

1. Protection of Future Generations. Radioactive waste shall be managed in such a way that predicted impacts on the health of future generations will not be greater than the relevant levels of impact that are acceptable today.

2. Burdens on Future Generations. Radioactive waste shall be managed in such a way that will not impose undue burdens on future generations.

In support of the proposed Part 63 dose limit, the NRC considered other current regulations for consistency and the potential effects of other sources of radiation to select a limit that would be acceptable today for releases of radiation. The EPA, ICRP, and NCRP have all supported the use of source-specific constraints (i.e., a margin of safety) below the 1 mSv/year (100 mrem/year) public dose limit to account for the potential effect of multiple sources of radiation exposure. In addition, use of the critical group concept or the RMEI provides an additional margin of safety because it is difficult for the same individual to be a member of the critical group or to be the RMEI for multiple diverse sources. The final regulations, which specify use of the RMEI concept and limit individual dose to 0.15 mSv/year (15 mrem/year) [15% of the public dose limit], are sufficiently protective that potential exposures from other sources (e.g., past releases from operations at NTS and future hospitals or research centers) would not be expected to result in exposures above the public dose limit.

^ 100 mrem/year

Issue 2: Why does NRC prefer an individual dose limit over a total release limit like

Part 60?

Comment. Some commenters, while noting that the EnPA specified a dose limit for Yucca Mountain, expressed their support for a total release limit like Part 60. The commenters believed that a total release limit is more understandable, easier to implement, and a simpler way to measure compliance of the repository's performance.

Response. The EPA has established a dose limit for individual protection, expressed in terms of a limit on dose to the RMEI. The NRC is incorporating this limit as required by law. A total release limit may appear to be more straightforward and understandable. In fact, however, nearly all of the same issues, such as dose or risk limit, human behavior, or volume of water mixed with the release, must be addressed to determine an appropriate release standard that is protective of the health and safety of the public and environment. Furthermore, a release standard is more difficult to relate directly to site-specific risk.

To set a release limit, the regulatory agency would first need to establish a risk or dose goal and calculate the risk or dose per unit release (e.g., per curie). The risk/dose goal would need to be the collective risk/dose over the entire compliance time for any release into the environment based on some assumed level of waste [e.g., for 40 CFR Part 191, EPA used a risk goal of 1,000 premature cancer deaths in 10,000 years per 100,000 metric tons of heavy metal contained in spent fuel (High-Level and Transuranic Radioactive Wastes: Background Information Document for Final Rule, Office of Radiation Programs, EPA 520/1-85-023, August 1985, Page 7-13)]. To calculate the risk per unit release, a model estimating the individual dose from a release will need to be used. To develop the model and data parameters, assumptions about the type of release [e.g., for 40 CFR Part 191, a release to surface water was assumed (ibid, pg. 7-13)], which biosphere processes to include, resource usage by the local

population [e.g., for 40 CFR Part 191, 65 percent of drinking water is assumed to be from the contaminated surface water (ibid, pg. 7-7)], and individual habits and characteristics [e.g., for 40 CFR Part 191, annual individual intake of drinking water is assumed to be 600 liters (ibid, pg. 7-7)] will need to be made. In its current form, Part 63 requires all the same calculations to be done, but the defense of many of the assumptions is the responsibility of DOE and will be subject to review and approval by NRC.

Use of a release limit also provides less information than calculating the dose from a release. The dose calculation combines the intake and exposure from all radionuclides in the environment into one term. The dose from one scenario or calculation can be readily compared to another. When release limits are used, it is very difficult to compare results if more than one radionuclide is involved because each radionuclide provides a different dose/risk per unit activity. For example, consider a review of two alternate designs. For design number one, the total release results in radionuclide A being released at 60 percent of its limit and radionuclide B is at 30 percent of its limit. For design number two, radionuclide A is 20 percent of its limit and radionuclide B is 70 percent of its limit. Without knowing the relative risk from a release per unit activity for each radionuclide, it would be difficult, if not impossible, to state which design results in a lower risk to the public. Thus, the total release limit is less insightful in its application than a dose limit. yields less information X

Issue 3: How does the use of an individual dose limit protect the entire population?

Comment. A few commenters supported either the use of collective dose limits or requiring dose distributions over the population to be calculated based on a concern that a single dose limit requiring only calculation of dose to the critical group would not adequately protect the overall population. Commenters (1) suggested that the collective dose is more important than

the individual dose, (2) disagreed with the use of a negligible individual dose value to screen possible release scenarios, and (3) viewed a dose distribution over the population as more informative to the regulators and public, allowing a more risk-informed decision to be made.

Response. The Commission agrees with NAS that "a health-based individual standard will provide a reasonable standard for protection of the general public" (p. 65 of the NAS report). The final regulations, which specify characteristics of a RMEI and an individual dose limit of 0.15 mSv/year (15 mrem/year), are protective of the RMEI. The general public includes the small number of individuals within the RMEI's community as well as all other individuals residing near the Yucca Mountain area. Because the community in which the RMEI resides will have a higher estimated dose than the highest exposed individual who does not live in that community, an individual dose limit for the RMEI is protective of all individuals.

While a distribution of individual doses for the entire population arguably can provide more information to consider in making a decision, the speculation and uncertainty regarding a representative population dose distribution would generally make the results inadequate to use in decision making. The difficulty lies in developing the habits, characteristics, location, and exposure time for the entire population. For analyses of possible future releases, such as from degrading waste in Yucca Mountain, the assumptions about the location, habits, and characteristics for each individual (or group of individuals) would be speculative. The Commission believes that it is possible to develop and defend a reasonable exposure scenario for a small group of individuals that would likely receive the largest doses based on current practices in the region because analyzing doses received by the RMEI living in a community at the 18-km (11-mile) location with a diet and living style representative of the people who now reside in the Town of Amargosa Valley, Nevada would bound any doses received by other individuals in the population. Because of the uncertainty in the distribution and range of activities,

including location and number of individuals, for other less exposed groups, unbounded speculation could make any resulting population dose distribution unsupportable.

While the Commission could require performance assessments of the potential dose distribution to hypothetical individuals, at the same locations and with the same habits as the current residents, the Commission believes that the uncertainty in the doses calculated for those not subject to the largest expected exposures would make the results difficult to interpret. In the end, the speculation would lead NRC, DOE, EPA, and other interested parties to expend resources without a commensurate increase in public health and safety or protection of the environment.

Collective dose is useful for comparing options but it does not provide adequate protection of the individual. Collective dose is the total dose received by all exposed people, regardless of distance or magnitude of exposure, over all time from a source. In general, most analyses tend to truncate the dose by calculating over a certain time frame and a given environmental area. Truncated collective dose can provide an overall measure of radiological impact on society or on parts of society but is only useful as an aid to compare options (e.g., DOE has considered individuals living within 84 km (52 miles) of the Yucca Mountain site for evaluating population doses in the DEIS). Because the calculation of collective dose results in a single value [in person-Sv (person-rem)], it gives no indication of the range or variability of individual doses or the time when the doses could occur. Meanwhile, the use of an individual dose limit to the RMEI assures that all other members of the population receive lower doses. The Commission believes that using an individual all-pathway dose assessment provides to the regulator and the public a meaningful measure for making decisions regarding public health and safety.

Issue 4: How is the "As Low As Reasonably Achievable" (ALARA) principle incorporated in Part 63?

Comment. A few commenters suggested that the ALARA principle be explicitly part of the long-term compliance dose limit in Part 63. Others supported the proposed rule for not including the ALARA principle in the requirements for the long-term performance requirements because the cost-benefit analysis would be highly speculative.

Response. The Commission believes that, ^{although} while it is appropriate to explicitly require the application of the ALARA principle to the operational and decommissioning phases of the repository, the application of ALARA to achievement of ^{the} long-term performance objective is not ^{appropriate}.

The ALARA principle deals with optimizing the reduction of potential doses from radiation to members of the general public and workers. It is a principal component of the radiation protection philosophy during operations and decommissioning activities and it helps to ensure that no individual will receive ^{a dose in excess of the} greater than his or her respective annual dose limit [i.e., 1 mSv/year (100 mrem/year) for the public and 50 mSv/year (5,000 mrem/year) for radiation workers]. Application of ALARA, during operations, compels the consideration of the benefits of further reduction in potential doses to present-day populations and workers relative to impacts to present-day populations (e.g., increased cost to reduce potential doses further). The application of ALARA to the achievement of the post-closure performance objective would involve considerations far more complicated than those evaluated for operations. The reasonableness of further reduction of potential doses would need to evaluate benefits and impacts that span many generations (e.g., costs incurred today versus a reduction of potential doses thousands of years in the future; repository designs that reduce potential doses in the future but increase doses to present-day workers during fabrication of the design such as installing a special backfill). By adopting the EPA's dose limit for long-term performance, the Commission implements a

constraint that is a small fraction (15 percent) of the public dose limit, and which provides a significant margin of safety to ensure that public health and safety and the environment are protected.

In its 1995 findings and recommendations, NAS noted that there is no scientific basis for incorporating the ALARA principle into NRC's Yucca Mountain regulations. In summary, their reasoning was that deep geologic disposal, by its very nature, was ALARA, and there were few technological alternatives in repository design. They also noted it would be problematic to evaluate compliance with the application of ALARA principles in the post-closure phase of the repository. The Commission agrees with NAS in this regard. Therefore, while the Commission will require ALARA considerations for the operational phase and decommissioning of the surface facilities, NRC will not explicitly require an ALARA analysis as part of the post-closure performance assessment.

Issue 5: Why did NRC select 0.25 mSv/year (25 mrem/year) as the proposed dose limit?

Comment. A large number of commenters addressed the 0.25 mSv/year (25 mrem/year) dose limit in proposed Part 63. A large number either disagreed with the limit, saying it was too high, or supported a lower standard such as the EPA's 0.15 mSv/year (15 mrem/year) standard in 40 CFR Part 191 and proposed 40 CFR Part 197. Some commenters (1) expressed confusion on whether the dose limit was for workers or members of the public, (2) requested additional clarification on what "fully protect" meant as part of the dose limit, or (3) supported the 0.25 mSv/year (25 mrem/year) dose limit.

Response. The purpose of the post-closure dose limit and the performance assessment is to ensure that future generations will be adequately protected. EPA has established, and the Commission ^{has} ~~will~~ incorporate, ^d a dose limit of 0.15 mSv/year (15 mrem/year). The Commission

+ ~~believes that this limit is fully protective, and has, in fact,~~ ^{its proposed} long held that the slightly higher dose limit of 0.25 mSv/year (25 mrem/year) to an individual is (1) a reasonable and appropriate fraction of the annual public dose limit to protect future generations from receiving doses greater than 1 mSv/year (100 mrem/yr), (2) within the range of dose limits used for current sources of public exposure, and (3) accounts for the possibility of dose from other sources. However, the Commission has changed the dose limit in the final rule in order to be consistent with EPA's final standards, ^{because it is required} ~~but not because the Commission is persuaded that its earlier proposal is unsafe in~~ ^{inadequate, or not appropriate} any way. The Commission is confident that the ~~even greater margin of safety afforded by the~~ 0.15 mSv/yr (15 mrem/yr) limit ^{also} is [^]amply protective. Both limits ensure that no member of the public would be exposed to more than 1 mSv/yr (100 mrem/yr) from all sources of radiation, except background radiation. Both protect future generations. During the operational phase, the repository will be required to comply with Part 20 for worker and public health and safety, except that the permitted public dose will be limited to 0.15 mSv/yr (15 mrem/yr).

^{Delete sent. 1 - it could be inferred that 25 mrem/yr was not low enough.} The Commission believes that the 0.15 mSv/yr (15 mrem/yr) dose established by EPA is so far below the public dose limit that no members of the public near Yucca Mountain would be expected to receive doses from all sources, excluding background radiation, in excess of 1 mSv/yr (100 mrem/yr). ^{Delete sent 2 - redundant w/ previous P.} Therefore, the Commission believes that by adopting a 0.15 mSv/yr (15 mrem/yr) limit to the RMEI, members of the general public will be fully protected.

Issue 6: How is NRC's proposed limit different than the dose limits in older rules (i.e., Part 61) and how do they compare?

Comment. Many commenters were concerned that the proposed Part 63 would relax health and safety standards. They (1) disagreed with the comparisons with other waste-related safety standards discussed in the Statements of Consideration of the proposed rule, especially

with rules using an older dose methodology and (2) expressed concern that the use of the single limit on the TEDE did not adequately protect the organs. They pointed to regulations requiring specific organ limits. While not a dose limit, some commenters disagreed with the use of the national value for background radiation for comparison for the Nevada area because of impacts from past practices.

Response. Part 63 does not change the 1 mSv/yr (100 mrem/yr) public dose limit from Part 20, which is the health and safety standard for protection of members of the public. The Commission adopts, in Part 63, a limit specifically for the repository, that is well below the public dose limit, and that is similar to, but more stringent than a number of other waste management-related dose limits. As noted in the proposed rule, the Commission considers 0.25 mSv/yr (25 mrem/yr) TEDE ^{to be} as the appropriate dose limit to compare with the range of potential doses represented by the older limits that had whole body dose limits of 0.25 mSv/yr (25 mrem/yr). The single limit does account for each organ's sensitivity to radiation, and each organ is limited to the same risk as the whole body. X

Different sources of radiation can have different constraints placed on them. The 0.25 mSv/yr (25 mrem/yr) dose limit is in a similar range as a number of other constraints for waste management facilities or decommissioning requirements (e.g. 40 CFR 191.03(a), 10 CFR 72.104, 10 CFR 61.⁴¹~~40~~, and 10 CFR 20.1402). Furthermore, during the operational and surface facility decommissioning phases, the facility will need to meet the ALARA requirements in 10 CFR 20.1101(b). This includes an 0.1 mSv/yr (10 mrem/yr) additional constraint on air emissions [10 CFR 20.1101(d)]. X

A number of the current regulations were published before the early 1990s when the NRC (and other Federal agencies) began using current knowledge about radiation risks and internal dosimetry. These older regulations generally have two or three limits associated with them.

They tend to have separate limits for the dose to the whole body, the organs, and possibly, a specific limit for the thyroid [e.g., 10 CFR 72.104 limit of 0.25 mSv/yr (25 mrem/yr) whole body, 0.75 mSv/yr (75 mrem/yr) thyroid dose, and 0.25 mSv/yr (25 mrem/yr) to any other critical organ]. At the time these older regulations were published, the Federal government was using a dosimetry system (i.e., a model that calculates the dose if a person ingests or inhales radioactive material) that did not account for the sensitivity to radiation of the various organs (also known as radiosensitivity) nor how the dose to an organ compared to a whole body dose. Because one could not add the various organ doses together, each needed its own limit. With little information on the radiosensitivity, most organs were given the same limit.

In the early 1990s, the Federal government began using a newer dosimetry system that accounted for how radiosensitive the various organ systems are. In addition to being able to compare the doses between organs, one can calculate what whole body dose would result in the same cancer risk. This whole body dose is known as an effective dose equivalent. By summing each organ's dose, weighted by its relative radiosensitivity, and adding in any whole body exposure, one could calculate the total dose received, which is called the TEDE. Therefore, by using the TEDE dosimetry system, not only the whole body but each of the organs are protected from an increased chance of cancer. They are also all protected at the same level of risk, which was not true of the earlier system.

Because each of the organs had the same limit under the older system even though each had a different level of radiosensitivity, it is very difficult to directly compare the old standards with the new standards. As noted in the proposed rule, the Commission considers 0.25 mSv/yr (25 mrem/yr) TEDE as the appropriate dose limit to compare with the range of potential doses represented by the older limits that had whole body dose limits of 0.25 mSv/yr (25 mrem/yr).

^{to conform to}
However, consistent with the EPA standards, the Commission has incorporated a dose limit of 0.15 mSv/yr (15 mrem/yr) in final Part 63. X

In the proposed rule, as a point of reference, it stated that the national average background radiation is approximately 3 mSv/yr (300 mrem/yr). Some commenters questioned whether this was valid for the Nevada area considering past practices in the area. The average background radiation stated in the proposed rule did not include variations due to the geology, relative altitude above sea level, or past practices in the region around Yucca Mountain. The Commission does not consider dose from the residual radioactivity left by past practices to be part of the background radiation and notes that EPA specifically accounted for these sources potentially exposing the RMEI in selecting the relevant dose limits for inclusion in its standards for Yucca Mountain.

3.3 Calculation of Expected Dose

Issue: Is the "expected annual dose" an appropriate quantitative measure for demonstrating compliance?

Comment. The public noted that while a specialist may know that the "expected dose" and the "mean dose" are equivalent, to many people "expected" implies the most likely outcome. The same commenter asserted that the mean value derived from the performance assessment is not the most likely, but rather a value that is unlikely to be exceeded. The commenter sought clarification on whether the "expected annual dose" is the mean or the median dose or some other statistical measure. Some members of the public approved of the use of the mean dose rather than the median or mode and noted that mean should provide a reasonable degree of conservatism. Furthermore, some commenters asserted that use of the "expected annual dose"

is completely consistent with NAS recommendations that the mean value of the calculations be used for comparison to the standard. Finally, one commenter supported the use of a 25 mrem performance objective, but suggested that it be bolstered with the addition of a 100 mrem limit on the 95th percentile of the probabilistic dose distribution.

Response. Final EPA standards at 40 CFR 197 specify that NRC determine compliance based upon the mean of projected doses of DOE's performance assessments. The Commission has incorporated this requirement at §63.303 in Subpart L. The mean of the projected annual dose is therefore the appropriate quantitative measure for demonstrating compliance with the dose limit. NAS recommended a performance objective for Yucca Mountain based on risk to an individual. Proposed Part 63 defined "risk" to an individual as being proportional to two factors: (1) the dose to the individual from exposure to ionizing radiation and (2) the probability of the individual receiving that dose. Analyses conducted by NRC staff demonstrate that the mean annual dose correctly expresses the risk from radioactive exposure to the individual.

The Commission expects that performance assessments conducted by the applicant in support of any potential license application will use probabilistic methods to simulate a wide range of possible, future behaviors of the repository system. Each possible future behavior of the repository system is represented by a curve describing the annual dose to the RMEI as a function of time. Generally, but not necessarily, each of the possible curves is assumed to be equally likely. Because none of these possible futures can be demonstrated to describe the actual future behavior of the repository system, the Commission requires that the applicant calculate the mean of these dose versus time curves, properly weighted by their individual probabilities.

In addition, NRC performance assessment experience indicates that the mean already reflects a high degree of confidence that dose limits will not be exceeded. For example,

community is conservative (i.e., protective). One commenter questioned the accuracy of the reported population count for Amargosa Valley.

Some commenters suggested alternative critical groups as being more representative or protective of the local population. Representatives of the Western Shoshone people suggested their long existence in the region and lifestyle in close proximity to the land support selection of a Western Shoshone critical group. They noted a long history of a hunting and gathering “subsistence” lifestyle that is expected to remain into the future. Farming and livestock activities were also discussed as recent introductions to the Western Shoshone lifestyle.

Response. While the Commission considers the proposed assumptions about the characteristics of the critical group to be protective of current and future populations in the vicinity of the site, the final rule has been changed, as required by EnPA, to use the mean dose to the RMEI, as defined at 40 CFR 197, as the measure to compare with the dose limit. While there are slight differences between the characteristics of EPA’s reasonably maximally exposed individual and the proposed average member of the critical group, they are practically the same. However, as noted, the Commission has adopted the characteristics of the RMEI, as specified in 40 CFR 197 and added two additional requirements.

Regarding the two additional requirements, the final regulations specify: (1) the water demand to be used in estimating exposure to the RMEI (see response to Issue 2 under Critical Group Location); and (2) that the RMEI is an adult with metabolic and physiological considerations consistent with present knowledge. Specification of the RMEI as an adult is: (1) consistent with the NAS recommendations for specifying the exposure scenario by rule; (2) consistent with the proposed regulation characteristics for the exposure scenario; (3) consistent with the criteria for the RMEI specified in the EPA standards (i.e., drinks 2 liters of water per day); and (4) consistent with the EPA’s Draft Federal Radiation Protection Guidance for Exposures of

X the General Public (59FR66422; December 23, 1994). The Commission considers the RMEI approach and associated characteristics of the RMEI ^{to be} protective of the health and safety of the public and environment (see also responses under Infant and Children Dose Standard and Location of the Critical Group or RMEI).

4 The Commission disagrees with the suggestions that a subsistence farming critical group should be used in dose calculations or that the RMEI be a subsistence farmer. As noted above, the Commission considers the RMEI approach from 40 CFR 197 to be fully protective. The RMEI approach requires DOE to use diet and living style representative of the people who now reside in the Town of Amargosa Valley, Nevada. Therefore, a variety of diets and lifestyles, including farming as it occurs today, will be represented in the characteristics of the RMEI. The Commission considers the use of local, present day conditions ^{to be} as the most realistic basis for RMEI behavior assumptions and present evidence indicates that there are no subsistence farmers in the vicinity of Yucca Mountain. NRC disagrees with the suggestion that the excessive conservatism of the subsistence approach is needed to offset any presumed lack of conservatism from the assumption of current conditions.

The Commission also disagrees with the suggestion that a Shoshone critical group should be used in dose calculations or that the RMEI be a Western Shoshone. In defining the critical group for the proposed rule, the Commission considered the possibility of a Native American based critical group. To date, based on all the information including the information provided by public comments, NRC has not been able to identify a suite of common characteristics of Native American groups in the region that is both different from the proposed farming critical group and likely to lead to greater exposures than the proposed farming critical group or the RMEI. Thus, the NRC believes the use of a RMEI for postclosure exposures protects Native Americans as well as other members of the public.

replaced with the RMEI for consistency with EPA's standards.

While it is beyond the capabilities of present-day science to determine "with certainty" that a future ice age will occur, the present paleoclimatic data support that (1) ice ages have occurred in past history, (2) climate changes in the past have exhibited a cyclical pattern, and (3) the cycle is likely to lead back to another ice age. The NRC has extensively investigated relevant research on future climate change in the vicinity of Yucca Mountain and has summarized the available information in an Issue Resolution Status Report (Nuclear Regulatory Commission. Issue Resolution Status Report Key Technical Issue: Unsaturated and Saturated Flow Under Isothermal Conditions, Revision 2, Vol 1. Washington DC: Nuclear Regulatory Commission, June 1999). The Commission encourages members of the public who are interested in the topic of past and future climate change in the vicinity of Yucca Mountain to obtain a copy of this report from the NRC Public Document Room (PDR) or from the NRC website (www.nrc.gov/NMSS/DWM/usfic.html). (For more information about obtaining reports from the NRC PDR, mail a request to U.S. Nuclear Regulatory Commission, Public Document Room, Mail Stop O1F13, Washington DC 20555, or e-mail pdrc@nrc.gov.) The NAS committee was also familiar with the science behind future climate changes and stated, in its recommendations on Yucca Mountain standards, that a future ice age in the next few hundred years is unlikely but not impossible, in the next 10,000 years is probable but not assured; however, over a million-year time frame, the climate is virtually certain to pass through several glacial-interglacial cycles (i.e., ice ages). The Commission believes there is sufficient information in the paleoclimate record to justify including climate change in the final regulations regarding effects on repository performance.

Climate change was included in the proposed regulations for the reference biosphere in § 63.115 because the NRC believed there was sufficient scientific evidence supporting the

potential for climate change over the long time frames considered by the performance assessment calculations. While NRC analyses suggest that inclusion of climate change in the biosphere is not likely to significantly change the local climate conditions and assumed exposure conditions, the Commission believes it is important to include the consideration for climate in both the geosphere and the biosphere performance assessment calculations to ensure that the conceptual model of the environment is consistent with our scientific understanding of reasonably anticipated natural events such as climate change. The NRC also believes it is important for DOE to include these processes in ^{its} ~~their~~ performance assessment calculations and do the necessary technical analyses to ensure the processes have been adequately considered and addressed.

The NRC agrees there is a need to emphasize current conditions when applied to behavioral characteristics of the RMEI. The natural systems of the biosphere are allowed to vary (e.g., climate change) because the geologic record provides evidence of past climate over a long time frame, which provides a strong basis for predicting future changes. Because human behavior cannot be similarly predicted, a similar approach cannot be used for the RMEI and the influence the local population has on the biosphere. Thus, a need exists to emphasize current conditions for the RMEI (see response to Issue 1 for more information). The suggestion that NRC consider alternative futures related to human behavior is speculative and leads to problems deciding which alternative futures are credible and which ones are unrealistic. Such issues have no scientific or technical answer. It is DOE's responsibility to demonstrate that the RMEI and biosphere assumptions in performance assessment calculations are consistent with local conditions. During the review of the license application, the NRC will evaluate DOE's assumptions to ensure they are consistent with current information. Given the uncertainties associated with local economics, NRC believes it is unreasonable to expect DOE to predict future

provide greater assurance for overall repository performance and, in general, supported keeping the quantitative limits at Part 60.

Response. The Commission believes that it presented a sound basis for the proposed approach to multiple barriers and defense in depth in the Supplementary Information accompanying the proposed Part 63. The final rule adopts a single quantitative performance goal for individual protection and separate limits for groundwater protection as specified by the EPA standards. Beyond these, the final rule does not place quantitative limits on individual barriers. After considering the comments received, however, the Commission recognizes a need to clarify the multiple barrier requirements in the proposed rule. The response to the next issue discusses the specific clarifications adopted.

The Commission based its proposed treatment of multiple barriers on the following:

1. Consistent with the Commission's risk-informed and performance-based regulatory philosophy, DOE is provided flexibility for deciding the extent and focus of site characterization. As the repository designer, DOE may place greater or lesser reliance on individual components of the repository system when deciding how best to achieve the overall safety objective.
2. Estimates of subsystem performance are subject to many, if not all, of the same sources of uncertainty as are estimates of overall system performance. It is questionable, therefore, whether the subsystem criteria in Part 60, or any others, ~~can~~ ^{could} provide truly independent assurance of total system performance. criteria
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3. The Commission recognizes that techniques of performance assessment have improved a great deal because of significant advances in knowledge and experience achieved since Part 60 was developed. These advances in performance assessment technology support the use of performance assessment

results for estimating long-term repository performance. They also obviate, in the Commission's view, the need to prescribe arbitrary, minimum performance standards for subsystems to build confidence in a system's overall performance.

The Commission's goal is to protect public health and safety and to assure compliance with EPA's standards. NRC's evaluation of DOE's compliance demonstration will examine how all components of the repository system work together to achieve this goal. Therefore, the proper emphasis should not be on the isolated performance of individual barriers but rather on ensuring the repository system is robust, and is not wholly dependent on a single barrier. Further, the Commission supports an approach that would allow DOE to use its available resources effectively to achieve the safest repository without unnecessary constraints imposed by separate, additional subsystem performance requirements. It is also important to remember that Part 63 requires DOE to carry out a performance confirmation program to provide further confidence that barriers important to waste isolation will continue to perform as expected (see Section 2.4 on Performance Confirmation).

Issue 2: How does the multiple barrier provision fulfill NRC's defense-in-depth philosophy in evaluating repository performance?

Comments. Some commenters asked the NRC to explain how we apply defense in depth to the repository without specific calculations or numerical limits for meeting this requirement. They stated that the proposed Part 63 is not clear about how DOE must demonstrate defense in depth for repository performance.

Response. In general, the Commission believes that a repository system should reflect the philosophy of defense in depth. The Commission expects that if a repository system is made up of multiple barriers, then it will be more tolerant of unanticipated failures and external

challenges. The final regulations specify criteria for quantitatively evaluating post-closure performance (e.g., individual protection, ground-water protection, and evaluation of human intrusion). These criteria help ensure defense in depth by requiring calculations that provide risk insights into the impact on performance of specific system attributes and external conditions. DOE must evaluate the performance of the repository system, as it performs as a result of compliance with general design criteria (e.g., required use of multiple barriers and identification of the repository by markers). DOE must also evaluate the system's response to various external challenges (e.g., disruptive events treated in the performance assessment, as well as a specified human intrusion scenario).

Commenters on the proposed rule pointed out that neither the intent of the multiple barrier provision, mandated by the Nuclear Waste Policy Act, nor how NRC would decide compliance with this provision, were clear. To clarify this intent, the final rule explains the concepts associated with the multiple barrier provision in § 63.102, and provides the associated technical criteria in § 63.115.

The proposed rule would have required DOE to: (1) identify barriers; (2) describe quantitatively each barrier's ability to contribute to waste isolation; and (3) provide technical bases for the barriers' capabilities as part of the overall demonstration of compliance with the individual protection standard (see § 63.114 (h)-(j) of the proposed rule). Although not necessarily required as a separate demonstration, this required information on the capability of barriers, integral to the performance assessment, illustrates the resilience, or lack of resilience of the repository to unanticipated failures or external challenges. Also, quantitative insights about defense in depth of the proposed repository emerge directly from the quantitative evaluations in the performance assessment. The performance assessment must include analyses of the effects of unlikely, but credible, external challenges on overall performance (In its analyses, DOE

must consider disruptive events that have an annual probability of occurrence greater than 10^{-8}). Disruptive events may degrade performance of the engineered barriers or reduce the effectiveness of natural barriers or both. Also, DOE must evaluate uncertainty about the performance of engineered barriers and that of the natural barriers in the performance assessment. For example, uncertainty about the corrosion rate of the waste package will necessarily affect the estimated lifetime of the package. Likewise, uncertainty about geochemical sorption will affect estimates of the time it takes specific radionuclides to travel in the geosphere. As with the disruptive events, the proper consideration of uncertainty in the performance assessment should assure an evaluation of the range of response of individual barriers to various challenges (e.g., higher than normal corrosion rates, lower than normal geochemical sorption). Thus, a complete performance assessment (*i.e.*, one that complies with §63.114) will illustrate the effectiveness of the multiple barriers, and the implementation of the philosophy of defense in depth, such that the individual protection standard is shown to be met even when barriers are challenged.

The Commission has clarified how DOE is to develop the technical basis for each barriers technical capability. The change makes clear that a description of relevant information, about a given barrier's characteristics and performance, that DOE has used to support the overall performance assessment, is sufficient to show compliance with this requirement. The language of the proposed rule was not intended to imply that an acceptable technical basis for multiple barriers need be (or even could be) derived separately from the basis for the performance assessment, itself. Rather, the technical basis for the barriers should be ~~a~~ presented in a focused, clear description. This description should be derived from pertinent information contained in the technical basis for the performance assessment.

Quantitative or Qualitative Assessment?

Consistent with the proposed rule, the final rule allows DOE to select from various methods to describe the capabilities of the barriers. Regardless of the method selected, DOE must describe the capability of each barrier to perform its intended function and the relationship of that barrier's role to limiting radiological exposure in the context of the overall performance assessment. The Commission has considered the comment that an evaluation of each barrier's capability should be quantitative. The Commission continues to believe a qualitative approach, as proposed, is appropriate for the following reasons:

1. It provides information to the Commission to be considered in its decisions without constraining its considerations to a specific limit for a particular barrier, which may result in less favorable overall system performance.
2. It provides flexibility to the Commission to consider the nature and extent of conservatism in the evaluations used for compliance demonstration, and for deciding whether there is a need to require DOE to reduce uncertainties in its assessment (e.g., collecting more site data) or to include further mitigative measures.
3. Quantitative evidence of the capability of individual barriers to contribute to waste isolation is an integral part of the performance assessment. Therefore, an additional quantitative limit is not necessary to show that overall performance reflects a system of multiple barriers.

The Commission understands that establishment of explicit, quantitative limits for individual barriers might be considered a desirable and more easily explained approach. That being said, however, the Commission knows of no scientific basis for setting such limits for

particular barriers at Yucca Mountain, or at any other site, independent of the complex repository system in which they must perform. The Commission is confident that evidence for the resilience, or lack of resilience, of a multiple-barrier system will be found by examining a comprehensive and properly documented performance assessment of the behavior of the overall repository system. Such an assessment must consider credible and supportable ranges of individual parameters and modeling assumptions, and must include multiple evaluations of a wide range of combinations of resulting barrier performance.

Finally, the required description of barrier capability provides information that will aid in the interpretation of the performance assessment results, while at the same time providing information that is independent from the condition of the other barriers. For example, the unsaturated and saturated zones could provide significant retardation to many radionuclides such that radionuclides will not reach the RMEI within 10,000 years regardless of when the waste package fails. This capability of geologic systems to "retard" or slow the movement of contaminants is present, and provides defense in depth, even when releases from the waste package are not occurring. Describing the capabilities of the system's component barriers (e.g., retardation of specific radionuclides in specific geologic media) can be accomplished by describing the applicable conceptual models and parameters used in the performance assessment. It does not require quantitative calculations beyond those performed to demonstrate compliance with the post-closure performance objectives. The Commission believes that understanding the capability of the system's component barriers provides an understanding of the repository system that ~~can~~ increases confidence that the post-closure performance objectives are met. The Commission is satisfied that the clarifying additions discussed above, along with other requirements at §§ 63.114 and 63.115, if met, will provide sufficient basis to determine whether a proposed repository system acceptably provides a system

of samples and data, scientific studies, performance of tests and experiments, controlling geological and engineering materials samples, facility design and equipment construction, facility operation, performance confirmation, permanent closure, and decontamination and dismantling of surface facilities. These terms are defined in § 63.2.

Based on the above discussion, the NRC considers the applicability of the QA program to be adequately described in Subpart G to Part 63. Because proposed Part 63 referred to Appendix B for QA requirements and Appendix B does not use the terms important to safety and important to waste isolation, requirements from Appendix B ^{have been} ~~will be~~ incorporated into final Part 63 and modified accordingly to address their applicability to the high-level waste repository. X

Issue 7: Should Part 63 contain QA program change controls similar to those found in § 50.54(a), and should the proposed § 63.44 change control process be applicable for QA program changes?

Comment. DOE identified a problem with proposed Part 63 requirements for controlling changes to the QA program and recommended that requirements similar to those contained in § 50.54(a) be used. DOE correctly pointed out that the NRC stated, in the discussion accompanying the final rule for Part 50 concerning changes to QA programs (64 FR 9030; February 23, 1999), that "use of 10 CFR 50.59 criteria for QA program changes is not appropriate." DOE pointed out that, as written, proposed Part 63 would permit QA program changes to be controlled in accordance with requirements similar to § 50.59 (as permitted by § 63.44). DOE suggested text changes to implement its comments. DOE also expressed a concern that as proposed, the location of § 63.21(c)(11) would cause the QA program description contained in the Safety Analysis Report to be subject to the change controls required by § 63.44.

Response. The Commission agrees that the use of the criteria specified at § 63.44 is not

appropriate for changes to the QA program description included in the Safety Analysis Report. We also agree that the rule should identify change control requirements applicable to the licensee's QA Program and that those requirements should be similar to those contained in § 50.54(a)(3). The proposed rule has been revised to specifically address change control requirements for QA program descriptions.

We disagree that § 63.21(c)(11) should be relocated to § 63.21(b) because the QA program description is required to specifically describe how the requirements of § 63.142 will be satisfied. By adding specific requirements in §§ 63.44 and 63.144 for the control of changes to the QA program description, the Commission believes it has resolved the expressed concern for relocating § 63.21(c)(11). [Note: The text at § 63.21(c)(11) in the proposed rule is specified at § 63.21(c)(17) in the final rule due to reordering of § 63.21 to achieve a more consistent order with the required analyses.]

Issue 8: How will NRC ensure DOE properly implements its QA program and assures the quality of data it will use to support a license application?

Comment. A number of comments related to what actions the NRC would take to ensure that DOE is properly implementing its QA program and qualifying data.

Response. In early 1999, the NRC staff established a QA Task Force to review and evaluate the DOE QA program. The Task Force was created to address acknowledged concerns regarding the effective implementation of the DOE QA program. This task force includes a Senior QA Engineer, the NRC Onsite Representatives, and the CNWRA QA Director, under the direction of the Division of Waste Management (DWM) Division Director. The Task Force has been active in reviewing DOE's progress and issues.

With respect to data qualification, DOE has initiated corrective actions for the data qualification problems documented in 1998 and 1999. In September 1999, DOE committed to have 100 percent of all data fully qualified by the time of license application, should DOE submit a license application. DOE has made significant progress in confirming the adequacy of data collected before June 1999. In January 2001, DOE had qualified 80 percent of these data. As of June 13, 2001, DOE had qualified 86 percent of the data supporting the potential license application. Further, during the June 13, 2001 ^{Qe}NRC/DOE Quarterly QA Breakout Session Meeting, DOE reported that its goal was to have all data fully qualified by site recommendation. X

In late spring of this year, NRC and DOE identified further QA problems, this time affecting the processes controlling software verification and model validation. DOE acknowledged a need to revise and enhance some of its procedures such as those controlling software development, and model validation and to provide needed training to its personnel. Further, DOE is evaluating traceability and transparency problems in its technical reports. The QA staff of DOE and their contractors have been successful in identifying the QA program deficiencies in the various participants' programs and, in many cases, highlighting the repetition of similar deficiencies. In the past, inadequate corrective action was taken, and the DOE organizations responsible for correcting the deficiencies were not held accountable. NRC has impressed upon DOE that correction of the QA program deficiencies is essential to any potential licensing of the Yucca Mountain repository and we are taking steps to ensure that NRC is able to evaluate the effectiveness of DOE action to correct the problem.

During fiscal year 2000 and through June 2001, the staff evaluated the implementation of DOE's QA program by: 1) continuing observation of DOE performance-based audits; 2) daily

overviews by NRC Onsite Representatives assigned to the Yucca Mountain Project office in Las Vegas, Nevada; 3) enhanced participation of NRC's technical staff in activities at the various DOE facilities; and 4) interfacing with DOE during technical exchanges and management meetings. Through these activities, we are encouraged that many of the deficiencies are being corrected by DOE. Further, we have observed that DOE is continuing to adequately identify, process, and correct new problems. NRC believes its aggressive overview activities provide the ability to adequately evaluate whether the DOE QA program will continue to be effectively implemented.

4.2 Changes, Tests and Experiments

Issue 1: Should the Commission adopt alternative criteria for changes, tests, and experiments?

Comments. Commenters who addressed the change process issue were generally supportive of applying alternative criteria, noting that the alternative criteria offered at § 63.44 were useful in clarifying the issues involved in evaluating the effects of changes, tests, and experiments on license conditions. Nonetheless, several commenters noted that the alternative criteria retained some terms that are ambiguous and that could be interpreted subjectively and recommended that such terms be avoided or defined in the final rule.

Response. For nuclear reactors, ISFSIs, and holders of a certificate of compliance for a spent fuel storage cask, the Commission recently amended its regulations concerning the authority of these licensees and certificate holders to make changes to the facility or operating procedures, or to conduct tests or experiments, without prior NRC approval (64 FR 53582; October 4, 1999). The final rule clarified the specific types of changes, tests, and experiments conducted at a licensed facility and revised the criteria that must be used to determine when

Whether DOE is subject to State law in obtaining any water rights that may be needed for this purpose is a matter to be determined by DOE and the State. The NRC does not have the authority to require that DOE conform to State law.

Comment. One commenter suggested that § 63.121(b) directly state that additional controls include water rights, instead of specifying in § 63.121(c)(2) that water rights are included in the additional controls to be established under § 63.121(b).

Response. The Commission prefers to retain the present format for clarity because water rights would be dealt with explicitly in one paragraph of § 63.121. "Controls" referred to in § 63.121(b) would, of course, include water rights.

Comment. One commenter viewed § 63.121 as giving DOE the right to take water rights in order to achieve waste isolation and stated that the rule must acknowledge the responsibilities of the Federal Government for compensation when initiating takings. This commenter was also concerned that the rule permits the spread of radionuclides to areas far outside the boundaries of the repository and believes that the repository should be designed so that it is not necessary to take water rights to achieve waste isolation. Another commenter believed that this regulation would allow Yucca Mountain to operate as a delayed radioactive waste release facility and not a permanent disposal site.

Response. Section 63.121 does not give DOE the right to take water rights; rather, it requires DOE to *have obtained* any water rights needed to achieve waste isolation. DOE will need to comply with whatever laws apply with respect to obtaining any needed water rights. The purpose of the regulation is to make sure that DOE is in a position to establish appropriate controls outside of the site necessary to prevent adverse human actions that could significantly reduce the geologic repository's ability to achieve waste isolation. The NRC will not license the

facility unless there is reasonable expectation that releases of radioactivity will remain within regulatory limits.

Issue 4: Do requirements for land ownership and control of the site apply equally to repository operations (pre-closure) and long-term safety (post-closure) activities?

Comment. DOE commented that requirements for land ownership and control (§ 63.121) are not sufficiently clear regarding their applicability to pre-closure and post-closure activities. The lack of a clear distinction between pre-closure and post-closure activities could imply that DOE must designate the same area for the evaluation of design basis events and for post-closure considerations for preventing adverse human actions. Part 60 provided flexibility in designating areas under pre-closure and post-closure activities that should be retained in Part 63.

Response. The Commission agrees with DOE that land ownership and control requirements are not sufficiently clear regarding their application to pre-closure and post-closure activities. The requirements ^{have been} ~~will be~~ clarified to indicate that: (1) the GROA shall be located in and on lands that are either acquired lands under the jurisdiction and control of DOE, or lands permanently withdrawn and reserved for its use; (2) DOE has the flexibility to identify and establish additional controls for lands outside the GROA necessary to prevent adverse human actions that could significantly reduce the geologic repository's ability to achieve isolation (post-closure); and (3) DOE has the flexibility to identify and establish additional controls for lands outside the GROA to ensure the requirements at § 63.111(a) and (b) are met. These clarifications have been made in revisions to § 63.121 of the final rule.

interact with the principal DOE staff engaged in site characterization activities. At this time, the NRC has no plans to expand the size of the onsite representative's office. However, the size of the office, as well as the scope of NRC's activities conducted there, is subject to reexamination. Meanwhile, the public is encouraged to contact our staff at the onsite representative's office at:

1551 Hillshire Drive, Suite A

Las Vegas, Nevada 89137-1048

Telephone 702/794-5046

Issue 4: Should AULGs and EPA be included in the regulations at Part 63, Subpart C, §§ 63.61 - 63.65, providing for participation in certain NRC regulatory activities?

Comment. One local government commenter noted that, under the NWPA, there is a legal basis for the participation of affected units of local government (AULGs) in activities concerning a potential repository at the Yucca Mountain site and asked why AULGs have not been included in § 63.61 and subsequent sections dealing with participation in regulatory activities. Another local government commenter explicitly requested that AULGs be included in the requirement for provision of "timely and complete information" in § 63.61. EPA also requested that it be included in § 63.61(a) given its interest in the proper implementation of the standards.

Response. Section 116(c) of the NWPA directs DOE to provide funding to AULGs so that they may participate in activities required or authorized under sections 116 and 117 of the NWPA. While these activities primarily involve DOE's interactions with the State, affected Indian tribes, and AULGs, the Commission believes that it would not be inconsistent with the intent of the statute to include AULGs at appropriate points in the regulations under Part 63, Subpart C, and has revised the regulations accordingly. The Commission is not adding EPA to §

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is consistent with
63.61(a) because this provision ~~mimics~~ section 117(a)(1) of the NWPPA which does not include EPA. However, the information provided under § 63.61(a) is available to EPA.

Issue 5: Should the “unquestionable legal right to participate as a party” in a repository licensing hearing afforded to the State of Nevada and any affected Indian Tribe in proposed § 63.63(a) also include affected units of local government (AULGs)?

Comment. A local government commenter stated that AULGs should have the same “unquestionable legal right to participate as a party” in a repository licensing hearing as is provided to the State of Nevada and any affected Indian Tribe in proposed § 63.63(a).

Response. The Commission agrees. The hearing procedures in the current 10 CFR Part 2, Subpart J, have replaced the hearing procedures in 10 CFR Part 2, Subpart G (except for sections of Subpart G specifically referenced in § 2.1000) with respect to a repository licensing proceeding. Under the Subpart J rules for intervention in the licensing proceeding, AULGs are permitted to intervene as a matter of right [see 54 FR 14938; April 14, 1989] in the same way as the State and an affected Indian Tribe. Thus, the Commission, in the final rule, has corrected the reference to “Subpart G” in the first sentence of § 63.63(a) to read “Subpart J” and has clarified the reference to local governments by changing it to “affected units of local government.” The Commission deleted the final sentence because it does not add any right not provided by the first sentence.

The proposed § 63.63(a) states: “State and local governments and affected Indian Tribes may participate in license reviews as provided in Subpart G of Part 2 of this chapter. The State of Nevada and any affected Indian Tribe shall have an unquestionable legal right to participate as a party in such proceedings.” This provision is modeled on, and virtually identical to, § 60.63(a). Section 60.63(a) was incorporated into NRC regulations prior to the Commission’s adoption of

The NRC staff will continue to provide information to explain the risks that would be associated with a repository licensed in accord with its regulations by using a variety of comparisons. The potential health effects arising from any radiation exposure is a very complex subject. To provide a context for NRC's proposed criterion of 0.25 mSv/yr (25 mrem/yr) or EPA's final limit of 0.15 mSv/yr (15 mrem/yr) individual dose limit for Yucca Mountain, NRC staff members frequently draw comparisons with other dose limits applied in NRC's regulation for low-level waste disposal (Part 61) as well as with national and international recommendations for radiation standards (see discussion under Individual dose limit). To provide some context for understanding what a radiation exposure at these levels represent, ⁵ comparisons have been made to the values for more "routine" radiation exposures (e.g., dental x-rays, increased radiation exposure from traveling in a plane). These comparisons are used to inform the public, not to persuade them. x

With respect to the meaning of the term "individuals with unusual habits and sensitivities," the Commission believes the commenter refers to the findings and recommendations of NAS. Both these recommendations and final EPA standards require that DOE base the characteristics of the representative group for post-closure dose calculations (the community in which the RMEI resides) on lifestyles and dietary habits (i.e., reliance on well water, extent to which food is grown locally, types of foodstuffs eaten) of individuals currently living in the Yucca Mountain region. NAS explained that specification of the representative group should avoid extreme cases defined by unreasonable assumptions regarding the factors affecting dose. NAS also stated that a reasonable and practicable objective is to protect the vast majority of members of the public while also ensuring that the decision on the acceptability of a repository is not prejudiced by the risks imposed on a very small number of individuals with "unusual habits or sensitivities" (pp. 51-52, "Technical Bases for Yucca Mountain Standard," National Research Council, 1995). Hence, the

terms “unusual habits” and “sensitivities” were used to exclude unreasonable assumptions about the from the characteristics of a hypothetical, future population group or RMEI. The Commission is quite certain that the NAS did not use these words to imply any judgment with regard to the behaviors or mental state of individuals residing near the site today. The Commission will continue to strive to explain more clearly complex technical and regulatory issues.

Issue 7: In the future, how is the NRC going to effectively communicate the risks of the Yucca Mountain Project to public health and safety?

Comment. One commenter requested one-on-one contact answering calls and letters and following through with questions and sending written responses. Another commenter was concerned that the people of Nevada are not suitably informed about the risks involved with the Yucca Mountain Project. Also, one commenter suggested that a bulletin be published quarterly or as an insert to a local paper about the Yucca Mountain Project. A few commenters were concerned that their fears are considered “irrational” regarding the safety of the Yucca Mountain Project and will not be taken seriously.

Commenters suggested that NRC use “local” sources (e.g., local government and libraries) to provide information to the public regarding meetings and other information. Information should be written in plain English.

Response. The NRC understands the importance of a strong public outreach program. NRC held five public meetings in Nevada during the public comment period on proposed Part 63. Comments made at those meetings were instrumental in NRC deciding to extend the public comment period for the proposed rule. However, these meetings also demonstrated to NRC that we can and need to do better in our public outreach efforts. The NRC has held seven additional public information workshops in Nevada since the public comment period closed on Part 63. We

will continue to meet with the people of Nevada and continue to seek the public's views on how we can carry out our responsibilities in a more effective manner. We also intend to keep the public better informed about our independent regulatory activities and oversight. The NRC will also continue to work on providing displays and fact sheets that use plain English.

The Commission notes also that DOE maintains three visitor centers that are intended to keep the public informed. They are located in Beatty, Pahrump, and Las Vegas. DOE also sponsors regular field trips to the Yucca Mountain site itself. Lastly, DOE maintains an Internet web page with information that is regularly updated on activities at the site and developments in the program; it can be found at <http://www.ymmp.gov>. With regard to the comments proposing that activities and future events be published in local newspapers, the NRC staff will forward that recommendation to DOE. As the repository developer, DOE has the responsibility to keep interested members of the public informed about activities at the site as well as about the program. ~~For those that are interested,~~ ^{the} State of Nevada, Nye County, Clark County, Eureka County, Inyo County, California, and others also maintain web sites with information about the Yucca Mountain program. They are located, respectively, at <http://www.state.nv.us/nucwaste>, <http://www.nyecounty.com>, <http://www.co.clark.nv.us/complan/Nucwaste.htm>, <http://Yuccamountain.org> and <http://sdsc.edu/Inyo/yucca-pg.htm>.

Finally, the Commission notes that the NRC staff has maintained a schedule of meetings with DOE on its web page (<http://www.nrc.gov/nmss/dwm/hlw/htm>) for several years. Important NRC documents related to the HLW program are also distributed to DOE. ^{Since} ~~Effective~~ November 1, 1999, ^{has made} ~~NRC is making~~ HLW program documents generated and received available on its Electronic Public Reading Room located at <http://www.nrc.gov/nrc/adams/index.html>. ^{NRC/ADAMS (capitals)} ~~nrc/adams~~ ^{two} Documents generated prior to November 1, 1999, can currently be found at the designated library reading rooms (in Nevada). ^{Insert - attached.}

Issue 8: How do the NRC and DOE, both as government agencies, maintain a proper relationship, respectively, as the regulator and a potential licensee?

Comment. One commenter was concerned that constant care needs to be taken by both NRC and DOE to maintain a relationship that clearly delineates between the regulator and the licensee.

Response. The NRC is developing a regulatory framework for the licensing of the proposed high-level waste repository with the promulgation of Part 63 and development of the Yucca Mountain Review Plan. This framework will clearly define the geologic disposal regulations DOE must meet and provide specific guidance to DOE on the information and evaluations necessary to demonstrate compliance with the regulations. As an independent regulatory agency, NRC's overall safety mission is to protect public health and safety, the environment, and common defense and security. NRC's regulatory role in any licensing action is to apply the applicable regulations and guidance, and to review applications for proposed actions to determine if compliance with regulations has been achieved.

The NRC Safety Philosophy will be applied to DOE's license application. This basic NRC Safety Philosophy, which is applicable to all the agency's licensing actions, is found in NRC's Strategic Plan. The underlying regulatory philosophy used by NRC in conducting its regulatory mission can be found in the section "Licensee Responsibility," which states the following:

"LICENSEE RESPONSIBILITY embodies the principal that, although NRC is responsible for developing and enforcing the standards governing the use of nuclear installations and materials, *it is the licensee who bears the primary responsibility for conducting these activities safely. The NRC's role is not to monitor all licensee activities but to oversee and audit them* [emphasis added]. This allows the agency to focus its inspection, licensing,

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most likely exposure scenario to radionuclides released from a potential geologic repository at Yucca Mountain would be in the ground water, down-gradient from the site. Because of this potential hazard, some commenters expressed the view that there is a need for the NRC to require that DOE implement a post-closure ground-water monitoring system. It was noted that such a system would protect citizens living near the repository by providing early-warning of the presence of radionuclides in the ground water.

Response. Consistent with the EnPA, Section 63.51(a)(3)(iii) requires a program for continued oversight of the repository site after permanent closure. One objective of the oversight program is to ensure that exposure to individual members of the public does not exceed allowable limits. Because the ground-water pathway is the most likely exposure pathway, it is expected that ground water would be monitored.

Issue 3: Would local residents be compensated if radioactive contamination, due to transport of HLW to Yucca Mountain or to leakage from the repository, damages their health or property?

Comment. Several commenters were concerned about whether local residents would be able to obtain compensation if their health should be adversely affected by leaking of radiation from the repository or from casks being transported to the repository. They were also concerned about whether damage to land or ground water due to radioactive contamination or to the lowering of property values would be compensated.

Response. Part 63 does not alter whatever liability the Federal Government may have for damage to health or property caused by its activities. It is possible that compensation could be available for certain types of damage to health or property under Federal law, but it would be speculative to suggest that compensation would be available in any particular case.

Issue 4: Over what time period must physical security be maintained over the site and how would this be maintained?

Comment. Some comments were made regarding how security would be maintained over the site for very long time periods. One commenter asked if the site would be safeguarded against sabotage.

Response. NRC's regulation requires that DOE will have a system of active institutional controls and (passive) site markers, specified at § 63.21(c)(18) [§ 63.21(c)(15) in the proposed rule] and § 63.51(3), that will prevent human intrusion into the repository by ensuring physical security indefinitely following permanent closure of any potential geologic repository at Yucca Mountain. That being said, by its very nature, geologic disposal is intended to provide a high degree of physical security by rendering the wastes difficult to access owing to their remote location deep underground (i.e., about 300 meters/1000 feet). As a practical matter, once the repository is closed – i.e., sealing and possibly backfilling of the underground drifts and access tunnels, the level of effort to reopen the repository and gain access to the wastes while preserving radiological safety will entail a substantial technical effort and expertise given current technology, and any action to do so would likely be detected.

As regards the potential risk of the repository ~~to~~ radiological sabotage^{to} during the pre-closure phase of operations, the Commission's regulations for Yucca Mountain at § 63.21(b)(3) require that licensees have in place adequate physical security plans and attendant procedures to protect against radiological sabotage, consistent with § 73.21 – NRC's regulations for the physical protection of nuclear plants (facilities) and nuclear materials.

Issue 5: Terminology in the rule is not always as clear as it should be.

In order to maintain an independent technical capability of the highest order, the NRC staff and its technical assistance consultants have been engaged in scientific investigations and research over the years necessary to understand how to properly regulate the management of radioactive wastes. The results of these efforts are widely published in the technical literature. In addition to these efforts, when there is a common interest, the NRC staff and its technical assistance consultants monitor or engage in international activities related to regulation or the advancement of technical capability related to the management of radioactive wastes. To oversee these activities, the Commission's ACNW makes recommendations, when appropriate, to adjust or expand the technical capabilities needed by its staff. X

In summary, the Commission believes that the qualifications and knowledge of the NRC staff and its technical assistance consultants in important technical aspects of the Yucca Mountain Project have the credentials, skills, and state-of-the-art knowledge that are necessary and appropriate to ensure that NRC regulatory decisions, with respect to public health and safety, are made with the highest degree of scientific competence.

Issue 7: Does Yucca Mountain fail to comply with one of the [technical] criteria in the existing (Part 60) rule?

Comment. A commenter noted that it appears from DOE analyses that the Yucca Mountain site does not comply with one of the specific criteria in the existing rule, not the proposed new rule.

Response. DOE has not submitted an analysis to NRC for review that would fit the description of this comment. In addition, this final rule amends 10 CFR 60.1 to clearly state that Part 63, not Part 60, applies to licensing a disposal facility at Yucca Mountain, Nevada. X

Issue 8: How should the material control and accounting program balance the need for inspections with worker exposures?

Comment. One commenter suggested that the program for maintaining material control and accounting should balance the need for periodic inspections with the potential for increased exposures of the inspectors. It was recommended that DOE and NRC should agree on how and when to terminate material control and accounting surveillance.

Response. The Commission agrees with the comment that workers should be protected from unnecessary doses due to repository operations. Although the requirement for conducting a physical inventory of HLW (reference to § 72.72 at § 63.78) extends over the operational period of the repository, the regulations provide flexibility to the Commission in determining the frequency for conducting the physical inventories. Determination of an appropriate frequency for conducting the inventories will consider such things as DOE's proposal for the material control and accounting program, the requirements for material control and accounting, and safety of inspectors. It is anticipated that the frequency for conducting inventories could vary due to significant changes in operations (i.e., emplacement versus post-emplacement activities) over the long operational period (e.g., 100 years) for the repository. The Commission considers a decision on how and when to terminate material control and accounting to be unnecessary and premature. The regulations provide the necessary flexibility for the Commission to determine how and when to terminate the material control and accounting that would consider the important issue raised by the commenter.

Issue 9: All references to "...decontamination or dismantlement..." of geologic repository facilities in the proposed rule (e.g., § 63.21) should be revised to refer to "...decontamination or decontamination and dismantlement..." to avoid confusion about the need for decontamination.

Comment. EPA suggested that the reference to decontamination and dismantlement in the proposed rule needed clarification because the current language implies that facilities that needed dismantlement did not need to be decontaminated.

Response. The Commission agrees with this comment and has revised the proposed rule as suggested.

Issue 10: Should there be additional requirements for the content of the application?

Comment. One commenter recommended that the contents of the license application at § 63.21(c)(1)(iv) should also include information on the hydrology, geology, and climate at and near the chosen location for the critical group.

Response. In general, the Commission agrees with this comment to the extent that the Commission anticipates that it will need such information because it has a bearing on understanding the lifestyles and habits of the RMEI. However, in the Commission's view, the type of information suggested by the commenter is already included in the regulations at § 63.21(c)(1). Nonetheless, the Commission expects that this subject will be addressed in the YMRP, which describes the required contents and methods for the NRC staff review of any potential DOE construction authorization application, as well as DOE's compliance demonstration with the rule. ~~The YMRP is currently under development by the staff and will be shared with interested stakeholders, as it is developed, and will be published for public comment. After the public comment period, the Commission will determine if additional revisions to the regulations are necessary (e.g., additional information to be included in the content of the application and a requirement for DOE to address all the issues in the YMRP).~~

At the appropriate time,
Based on the public comments received, the staff
YMRP or
(As written, its release sounds imminent.)

Issue 11: Does the requirement for collecting information during construction (§ 63.72) take precedence over preservation of the design integrity?

Comment. It should be recognized that there is the possibility that the collection of certain types of data could have a negative effect on the waste isolation capabilities of the site. The proposed requirements found in § 63.72 should be modified to recognize that data should be collected only when it is determined that the activities will have no adverse effect on the long-term performance of the repository.

Response. The Commission shares the commenter's concern that the collection of data could (potentially) have an adverse effect on the long-term performance of the repository. In this regard, it should be noted that the Commission is not in favor of any particular data collection techniques nor would it encourage data collection that could potentially affect the long-term performance of the repository or the effectiveness of its barriers be they natural or engineered. Nonetheless, during repository construction, DOE will need to collect data to confirm certain design (and performance) parameters as well as to identify previously undetected geologic conditions so as to have confidence that the repository will function as intended. To ensure that these activities have no effect on long-term repository performance, consistent with section 113(b)(1)(A)(ii) of the NWPA, DOE will need to describe its data collection plans during construction in the manner described in § 63.72 so that their effect, if any, on containment and waste isolation can be independently evaluated by the NRC staff.

Issue 12: The reference to § 63.51(a)(2) (post-closure monitoring program) in §§ 63.71(b) (records and reports) and 63.72(a) (construction records) should be changed to refer to § 63.51(a)(3) (measures to regulate or prevent activities that could impair repository long-term performance).

commenter strongly opposed any suggestion to depart from formal trial-type adjudicatory and evidentiary hearing rules in 10 CFR Part 2 for this potentially complex and first of a kind licensing proceeding.

Response. In the proposed rule, the Commission told commenters that it had a broad study of the NRC hearing process underway, including the process that would be used for repository licensing. The Commission stated that it was inclined to provide for informal hearings for both construction authorization and licensing to receive and possess waste. If the Commission were to conclude that changes to the hearing process are warranted, the Commission stated that it would propose them for adoption in a separate notice and comment rulemaking. For that reason, the Commission did not seek comments on potential changes to the hearing process in this rulemaking. Subsequently, the Commission finished its study of the NRC hearing process and directed the staff to prepare a proposed rule to provide changes ^{to} of that process. The proposed rule was published on April 16, 2001 (66 FR 19610) and the comment period closes on September 14, 2001. *(extension of comment period 66 FR 27045; May 16, 2001)*. In this recent notice, the Commission proposes to use formal hearing procedures in proceedings for the initial authorization to construct a geologic repository operations area and proceedings for initial authorization to receive and possess high-level waste at the repository. However, amendments to the construction authorization and to the authorization to receive and possess high-level waste may be conducted under informal hearing procedures. See proposed section 2.310(e). The Commission will make its final determinations on these issues in a final rule after it has considered all public comments received in this separate rulemaking. X

6.2 Transportation

Issue 1: What regulations or controls will be used to ensure nuclear waste is transported safely including operations at an intermodal transfer facility?

Comment. Commenters raised concern that the risks for transporting nuclear waste were not being addressed in proposed Part 63. Many commenters interpreted the absence of transportation criteria in proposed Part 63 as an indication that NRC has deemphasized transportation issues. One commenter raised concern over the possibility of terrorism and theft of spent fuel shipments.

Response. Nuclear waste transportation safety is not specifically addressed by the proposed Part 63 because it is beyond the scope of this rulemaking. Issues related to terrorism or theft of spent fuel shipments during transport are also beyond the scope of this Part 63 rulemaking. Nothing in this rule changes the existing regulatory regime governing the transportation of spent nuclear fuel and high-level radioactive waste.

Section 180 of the NWPA requires DOE to use packages that have been certified by NRC for transportation of spent nuclear fuel and HLW. The NRC regulations in 10 CFR Part 71 specify the standards for certification. These standards provide that a package must prevent the loss or dispersion of radioactive contents, provide adequate shielding and heat dissipation, and prevent nuclear criticality under both normal and accident conditions of transportation.

Section 180 of the NWPA also requires that DOE abide by NRC regulations regarding advance notification of State and local governments prior to transportation of spent nuclear fuel or high-level radioactive waste. Such advance notification requirements are set forth in 10 CFR 73.37. The NWPA also requires DOE to provide funds and technical assistance for training of local public safety officials (e.g., emergency responders) along the routes.

In Volume II of the *Draft Environmental Impact Statement for a Geologic Repository for the Disposal of Spent Nuclear Fuel and High Level Radioactive Waste at Yucca Mountain, Nye*

County, Nevada, dated July 1999 (DEIS) (at J-23), DOE states that its proposed procedures for implementing Section 180 of the NHPA provide that routing for shipments to Yucca Mountain would comply with applicable regulations of the U.S. Department of Transportation (DOT) in effect at the time of such shipments. DOT regulations on route approval for transporting radioactive material by highway and State or Tribal designation of preferred routing [as an alternative to Interstate System highways] are contained in 49 CFR ^{§§} 397.101, 397.103, and 397.201. X

A DOT-NRC Memorandum of Understanding (44 FR 38690; July 2, 1979) specifies that, in general, the DOT is responsible for regulating safety in transportation of all hazardous materials, including radioactive material. The NRC is responsible for regulating safety in receipt, possession, use, and transfer of radioactive materials. The NRC also reviews and approves package designs for transporting fissile material and other radioactive material in quantities exceeding Type A limits. Facilities which temporarily handle and store radioactive material during and incidental to their transport (i.e., movement), such as operations at an intermodal transfer facility, are subject to DOT requirements.

Issue 2: How will transportation routes be selected and will local governments and communities be informed and consulted about the routes?

Comment. Commenters raised a number of questions regarding the selection of transportation routes for nuclear waste, such as: (1) Will DOE analyze the impacts of transportation routes; (2) Can rural roads be used to safely transport large nuclear waste shipments; (3) Will transportation route selection be addressed in DOE's license application; (4) Will local governments and communities be able to participate in route selection; and (5) Does

NRC require DOE contractors to be responsible for transporting waste or are third-party contractors responsible for transporting waste.

Response. The routing requirements and practices largely depend upon whether a particular shipment is made by highway or railway. DOE is evaluating its options regarding the mix of road and rail shipments to the potential repository and will decide the appropriate level of analysis needed for transportation routes.

As noted above, DOE has stated that routing of shipments of spent nuclear fuel and high-level waste will comply with applicable DOT regulations (DEIS, Vol. II, at J-23). The DEIS (Vol. I and Vol. II, Appendix J) also contains a discussion of the impacts associated with shipments to the proposed repository. The DOT regulations (49 CFR Part 397) provide that shipments are to be on preferred routes (Interstate System highways and city bypasses) or State- or Tribal-designated preferred routes (i.e., alternate routes). These routing requirements were developed by the DOT considering the risks of transportation. Further, DOT has published guidelines (DOT/RSPA/HMS/92-02) for State or Tribal agencies to use in performing route analyses to ensure that the overall risk of the shipments to the public is considered in designating preferred routes. The degree of local participation in the State or Tribal routing agency's process may vary from State to State or from Tribe to Tribe.

NRC licensees, contractors of NRC licensees, DOE, and DOE contractors who are transporting spent fuel by highway must abide by the DOT's routing rules when they transport spent fuel by highway. There are no Federal regulations for selecting railway routing. Once a highway or railway route is selected, the route is reviewed by the NRC for physical protection purposes. NRC annually publishes a report, "Public Information Circular for Shipments of Irradiated Reactor Fuel" (NUREG-0725, Rev. 13, 1998), that describes the routes taken by commercial spent fuel shipments. For physical protection reasons, certain information on

Comment. A commenter wanted to know how much money had been spent on the Yucca Mountain project.

Response. The DOE publishes reports that give details of its budget and spending on the Yucca Mountain project. Expenditures are the subject of appropriations by Congress and oversight by both Congress and the General Accounting Office. In May 2001, DOE published its most recent cost estimates [see "Analysis of the Total System Lifecycle Costs of the Civilian Radioactive Waste Management Program," DOE/RW-0533, May 2001; available on DOE's web page at <http://www.rw.doe.gov>]

Issue 6: What happens if the Yucca Mountain project is developed and Congress cuts the budget for it? Or appoints a weaker agency to oversee the project?

Comment. A commenter noted that Congress had cut DOE's budget for Yucca Mountain in past years. What will NRC do, especially regarding monitoring, if construction of the project is underway, and a budget cut occurs?

Response. Responsibility for the Yucca Mountain project rests with DOE. Changes in budget levels for the Yucca Mountain project would have to be addressed by DOE in its planning for the project. If the Commission believes that it does not have sufficient funds to carry out its mission to protect public health and safety, it would ask Congress for additional funding.

Issue 7: Will the NRC staff seek input from local governments to assist it in providing comments to the DOE on the DEIS for Yucca Mountain?

Comment. One commenter asked the NRC to seek input from local governments to assist the NRC in providing comments on the DOE's DEIS.

Response. The NRC is not required by NWPAA to solicit and forward comments to DOE from the AULGs or anyone else during the DEIS public comment period. The NRC is expected, under the NWPA, to comment on the DEIS during the DEIS public comment period. The NRC provided comments for DOE to consider as part of the DEIS public comment process. In preparing these comments, the NRC staff observed DOE's DEIS public meetings to better understand what DEIS issues were of concern to the public. In addition, the NRC staff conducted its own meetings with AULG officials and conducted a public meeting in Caliente (Nevada) to discuss the NRC role with respect to the EIS, as it was formulating its comments. For its part, the Commission invited AULGs, stakeholders, and other interested parties to express their views on the DEIS during a public meeting on January 21, 2000. The Commission has considered these views before forwarding its comments to DOE.

Issue 8: Does the public have enough time to prepare comments on DOE's DEIS for Yucca Mountain and attend NRC meetings on Part 63?

Comment. The NRC staff was asked at several public meetings to avoid scheduling future public workshops and meetings on Part 63 during the DEIS public comment period.

Response. The Commission is sensitive to the issue being raised here and notes that the NRC is making every effort practical to schedule its public workshops and meetings in such a way so as to afford the public opportunity to participate in other agencies' activities. Accordingly, the Commission held only one meeting on Part 63 during the public comment period on the DEIS.

Issue 9: What about the possibility that a waste repository at Yucca Mountain would be a target in the event of a nuclear war?

The record retention requirements referenced at §63.72(a) were incorrect in the proposed rule and have been modified to refer correctly to § 63.51(a)(3). Additionally, the design specifications and “as built” drawings have been added to the list of required records.

Section 63.73 Reports of deficiencies.

The phrase “[b]e a substantial safety hazard,” found at § 63.73(a)(1), was replaced with the phrase “[a]dversely affect safety at any future time,” to be consistent with terminology used at § 63.32(b)(3) and to avoid confusion with reporting requirements under 10 CFR Part 21, which includes a very precise definition for what constitutes a “substantial safety hazard.” Specific requirements regarding DOE’s implementation of a program for evaluating and reporting deficiencies have been included to clarify the reporting requirements.

Subpart E - Technical Criteria

Section 63.101 Purpose and nature of findings.

This section has been revised to address how the Commission intends to implement a finding of reasonable expectation. The discussion of postclosure performance objectives has been revised to conform with the public health and environmental radiation standards for geologic disposal now specified in subpart L, which are referenced in § 63.113.

Section 63.102 Concepts.

This section has been changed to clarify NRC’s expectations for the demonstration of compliance with the requirements for multiple barriers, performance confirmation, and preclosure safety analysis. The discussion of multiple barriers has been modified to clarify the intent of the

multiple barrier requirement. The discussion of preclosure safety analysis has been revised to clarify requirements for the dose calculations due to the event sequences and the selection of specific event sequences to be included in the analysis. The discussion of performance confirmation has been revised to more clearly reflect the intent of the general requirements for performance confirmation at § 63.131(a). Additional changes have been made to conform with the final 40 CFR Part 197, including among others the discussion of the *reference biosphere*, *reasonably maximally exposed individual*, and *human intrusion*; and addition of a discussion on *ground-water protection*.

Section 63.111 Performance objectives for the geologic repository operations area through permanent closure.

X Section 63.111(a)(2) has been modified to conform with the individual protection standard now specified in subpart L. [Describe revisions to §§ 63.111(b) 1 and 2. — see response to issue 3 on p. 37]

Section 63.112 Requirements for preclosure safety analysis of the geologic repository operations area.

This section has been revised to clarify that the objective of the analysis is to evaluate event sequences; as such, the phrase “accidents that would result in unacceptable consequences” has been replaced with event sequences. The consideration of criticality has been clarified by requiring analysis of the means to prevent and control criticality. The words “principal design criteria” have been replaced with “design criteria” to be consistent with the changes made at § 63.21 (as noted in the discussion under § 63.21 this change was not intended as a substantive change).

impact statement and any supplements, must be signed by the Secretary of Energy or the Secretary's authorized representative and must be filed in triplicate with the Director.

(b) DOE shall submit 30 additional copies of each portion of the application and any amendments, and each environmental impact statement and any supplements. DOE shall retain another 120 copies for distribution in accordance with written instructions from the Director or the Director's designee.

(c) On notification of the appointment of an Atomic Safety and Licensing Board, DOE shall update the application, eliminating all superseded information, and supplement the environmental impact statement if necessary, and serve the updated application and environmental impact statement (as it may have been supplemented) as directed by the Board. Any subsequent amendments to the application or supplements to the environmental impact statement must be served in the same manner.

(d) When an application, and any amendment to it is filed, copies must be made available in appropriate locations near the proposed geologic repository operations area at the Yucca Mountain site for inspection by the public. These copies must be updated as amendments to the application are made. The environmental impact statement and any supplements to it must be made available in the same manner. An updated copy of the application, and the environmental impact statement and supplements, must be produced at any public hearing held by the Commission on the application for use by any party to the proceeding.

(e) DOE shall certify that the updated copies of the application, and the environmental impact statement as it may have been supplemented, as referred to in paragraphs (c) and (d) of this section, contain the current contents of these documents submitted as required by this part.

§ 63.23 Elimination of repetition.

In its application or environmental impact statement, DOE may incorporate, by reference, information contained in previous applications, statements, or reports filed with the Commission, if the references are clear and specific and that copies of the information incorporated are made available to the public locations near the site of the proposed geologic repository, as specified in § 63.22(d).

§ 63.24 Updating of application and environmental impact statement.

X (a) The application must be as complete as possible in the light of information that is reasonably available at the time of docketing.

(b) DOE shall update its application in a timely manner so as to permit the Commission to review, before issuance of a license --

(1) Additional geologic, geophysical, geochemical, hydrologic, meteorologic, materials, design, and other data obtained during construction;

(2) Conformance of construction of structures, systems, and components with the design;

(3) Results of research programs carried out to confirm the adequacy of designs, conceptual models, parameter values, and estimates of performance of the geologic repository.

(4) Other information bearing on the Commission's issuance of a license that was not available at the time a construction authorization was issued.

(c) DOE shall supplement its environmental impact statement in a timely manner so as to take into account the environmental impacts of any substantial changes in its proposed actions or any significant new circumstances or information relevant to environmental concerns bearing on the proposed action or its impacts.

CONSTRUCTION AUTHORIZATION

PERMANENT CLOSURE

§ 63.51 License amendment for permanent closure.

(a) DOE shall submit an application to amend the license before permanent closure of a geologic repository at the Yucca Mountain site. The submission must consist of an update of the license application submitted under §§ 63.21 and 63.22, including:

(1) An update of the assessment of the performance of the geologic repository for the period after permanent closure. The updated assessment must include any performance confirmation data collected under the program required ^{by g} under Subpart F, and pertinent to compliance with § 63.113. 4

(2) A description of the program for post-permanent closure monitoring of the geologic repository.

(3) A detailed description of the measures to be employed — such as land use controls, construction of monuments, and preservation of records — to regulate or prevent activities that could impair the long-term isolation of emplaced waste within the geologic repository and to assure that relevant information will be preserved for the use of future generations. As a minimum, these measures must include:

(i) Identification of the site and geologic repository operations area by monuments that have been designed, fabricated, and emplaced to be as permanent as is practicable;

(ii) Placement of records in the archives and land record systems of local, State, and Federal government agencies, and archives elsewhere in the world, that would be likely to be consulted by potential human intruders — such records to identify the location of the geologic

repository operations area, including the underground facility, boreholes, shafts and ramps, and the boundaries of the site, and the nature and hazard of the waste; and

(iii) A program for continued oversight, to prevent any activity at the site that poses an unreasonable risk of breaching the geologic repository's engineered barriers; or increasing the exposure of individual members of the public to radiation beyond allowable limits.

(4) Geologic, geophysical, geochemical, hydrologic, and other site data that are obtained during the operational period, pertinent to compliance with § 63.113.

(5) The results of tests, experiments, and any other analyses relating to backfill of excavated areas, shaft, borehole, or ramp sealing, drip shields, waste packages, interactions between natural and engineered systems, and any other tests, experiments, or analyses pertinent to compliance with § 63.113.

(6) Any substantial revision of plans for permanent closure.

(7) Other information bearing on permanent closure that was not available at the time a license was issued.

(b) If necessary, to take into account the environmental impact of any substantial changes in the permanent closure activities proposed to be carried out or any significant new information regarding the environmental impacts of permanent closure, DOE shall also supplement its environmental impact statement and submit this statement, as supplemented, with the application for license amendment.

§ 63.52 Termination of license.

(a) Following permanent closure and the decontamination or decontamination and dismantlement of surface facilities at the Yucca Mountain site, DOE may apply for an amendment to terminate the license.

(b) In addition, a State, or an affected unit of local government, or an affected Indian Tribe may submit a proposal to the Director to facilitate its participation in the review of the license application. The proposal may be submitted at any time and must contain a description and schedule of how the State, or affected unit of local government, or affected Indian Tribe wishes to participate in the review, or what services or activities the State, or affected unit of local government, or affected Indian Tribe wishes the NRC to carry out, and how the services or activities proposed to be carried out by the NRC would contribute to this participation. The proposal may include educational or information services (seminars, public meetings) or other actions on the part of NRC, such as establishing additional public document rooms or employment or exchange of State personnel under the Intergovernmental Personnel Act.

(c) The Director shall arrange for a meeting between the representatives of the State, or affected unit of local government, or affected Indian Tribe and the NRC staff, to discuss any proposal submitted under paragraph (b) of this section, with a view to identifying any modifications that may contribute to the effective participation by such State, or affected unit of local government, or Tribe.

(d) Subject to the availability of funds, the Director shall approve all or any part of a proposal, as it may be modified through the meeting described in paragraph (c) of this section, if it is determined that:

(1) The proposed activities are suitable in light of the type and magnitude of impacts that the State, or affected unit of local government, or affected Indian Tribe may bear;

(2) The proposed activities --

(i) Will enhance communications between NRC and the State, or affected unit of local government, or affected Indian Tribe;

(ii) Will make a productive and timely contribution to the review; and

(iii) Are authorized by law.

X (e) The Director shall advise the State, or affected unit of local government, or affected Indian Tribe whether its proposal has been accepted or denied. If all or any part of proposal is denied, the Director shall state the reason for the denial.

(f) Proposals submitted under this section, and responses to them must be made available at the Public Document Room.

§ 63.64 Notice to State.

If the Governor and legislature of the State of Nevada have jointly designated, on their behalf, a single person or entity to receive notice and information from the Commission under this part, the Commission will provide the notice and information to the jointly designated person or entity instead of the Governor and legislature separately.

§ 63.65 Representation.

Any person who acts under this subpart as a representative for the State of Nevada (or for the Governor or legislature of Nevada), for an affected unit of local government, or for an affected Indian Tribe shall include in the request or other submission, or at the request of the Commission, a statement of the basis of his or her authority to act in this capacity.

Subpart D — Records, Reports, Tests, and Inspections

§ 63.71 Records and reports.

(a) DOE shall maintain records and make reports in connection with the licensed activity that are required by the conditions of the license or by rules, regulations, and orders of the Commission, as authorized by the Atomic Energy Act and the Energy Reorganization Act.

(b) Records of the receipt, handling, and disposition of radioactive waste at a geologic repository operations area at the Yucca Mountain site must contain sufficient information to provide a complete history of the movement of the waste from the shipper through all phases of storage and disposal. DOE shall retain these records in a manner that ensures their usability for future generations in accordance with § 63.51(a)(3).

§ 63.72 Construction records.

(a) DOE shall maintain records of construction of the geologic repository operations area at the Yucca Mountain site in a manner that ensures their usability for future generations in accordance with § 63.51(a)(3).

(b) The records required under paragraph (a) of this section must include at least the following --

- (1) Surveys of the underground facility excavations, shafts, ramps, and boreholes referenced to readily identifiable surface features or monuments;
- (2) A description of the materials encountered;
- (3) Geologic maps and geologic cross-sections;
- (4) Locations and amount of seepage;
- (5) Details of equipment, methods, progress, and sequence of work;
- (6) Construction problems;
- (7) Anomalous conditions encountered;
- (8) Instrument locations, readings, and analysis;

- (9) Location and description of structural support systems;
- (10) Location and description of dewatering systems;
- (11) Details, methods of emplacement, and location of seals used; and
- (12) Facility design records (e.g, design specifications and "as built" drawings).

§63.73 Reports of deficiencies.

(a) DOE shall promptly notify the Commission of each deficiency found in the characteristics of the Yucca Mountain site, and design, and construction of the geologic repository operations area that, were it to remain uncorrected, could --

- (1) Adversely affect safety at any future time;
- (2) Represent a significant deviation from the design criteria and design basis stated in the design application; or

? *significant?* (3) Represent a [✓]deviation from the conditions stated in the terms of a construction authorization or the license, including license specifications.

(b) DOE shall implement a program for evaluating and reporting deviations and failures to comply, to identify defects and failures to comply associated with substantial safety hazards, based on the applicable requirements in 10 CFR 50.55(e) as it applies to the construction authorization and design of the geologic repository operations area at the Yucca Mountain site.

(c) DOE shall implement a program of reporting specific events and conditions that is the same as that specified in 10 CFR 72.75.

(d) The requisite notification must be as specified in the applicable regulation. Copies of the written report must be sent to the NRC Operations Center, Document Control Desk, U.S. NRC, the Director of NMSS, U.S. NRC, and to the NRC onsite representative.

(a)(1) Subpart B prescribes the standards for issuance of a license to receive and possess source, special nuclear, or byproduct material at a geologic repository operations area at the Yucca Mountain site. In particular, § 63.41(c) requires a finding that the issuance of a license will not constitute an unreasonable risk to the health and safety of the public. The purpose of this subpart is to set out the performance objectives for postclosure performance of the geologic repository and other criteria that, if satisfied, support a finding of no unreasonable risk. Postclosure performance objectives for the geologic repository include a requirement to limit radiological exposures to the reasonably maximally exposed individual, a requirement to limit releases of radionuclides to the accessible environment to protect ground water, and a requirement to limit radiological exposures to the reasonably maximally exposed individual in the event of human intrusion (see §§ 63.113(b), (c), and (d), respectively).

(2) Although the postclosure performance objectives specified at § 63.113 are generally stated in unqualified terms, it is not expected that complete assurance that the requirements will be met can be presented. A reasonable expectation, on the basis of the record before the Commission, that the postclosure performance objectives will be met, is the general standard required. Proof that the geologic repository will conform with the objectives for postclosure performance ^{is} not to be had in the ordinary sense of the word because of the uncertainties inherent in the understanding of the evolution of the geologic setting, biosphere, and engineered barrier system. For such long-term performance, what is required is reasonable expectation, making allowance for the time period, hazards, and uncertainties involved, that the outcome will conform with the objectives for postclosure performance for the geologic repository. Demonstrating compliance will involve the use of complex predictive models that are supported by limited data from field and laboratory tests, site-specific monitoring, and natural analog studies that may be supplemented with prevalent expert judgment. Compliance demonstrations should

not exclude important parameters from assessments and analyses simply because they are difficult to precisely quantify to a high degree of confidence. The performance assessments and analyses should focus upon the full range of defensible and reasonable parameter distributions rather than only upon extreme physical situations and parameter values. Further, in reaching a determination of reasonable expectation, the Commission may supplement numerical analyses with qualitative judgments including, for example, consideration of the degree of diversity among the multiple barriers as a measure of the resiliency of the geologic repository.

X (b) Subpart B lists findings that must be made in support of an authorization to construct a geologic repository operations area at the Yucca Mountain site. Prior to closure, § 63.31(a)(1) requires a finding that there is reasonable assurance that the types and amounts of radioactive materials described in the application can be received, possessed, and stored in a geologic repository operations area of the design proposed without unreasonable risk to the health and safety of the public. After permanent closure § 63.31(a)(2) requires the Commission to consider whether there is a reasonable expectation the site and design comply with the postclosure performance objectives. Once again, although the criteria may be written in unqualified terms, the demonstration of compliance must take uncertainties and gaps in knowledge into account so that the Commission can make the specified finding with respect to paragraph (a)(2) of § 63.31.

§ 63.102 Concepts.

This section provides a functional overview of this Subpart E. In the event of any inconsistency, the definitions in § 63.2 prevail.

(a) *The HLW facility at the Yucca Mountain site.* NRC exercises licensing and related regulatory authority over those facilities described in Section 202 (3) and (4) of the Energy

operation to identify any significant changes in the conditions assumed in the license application that may affect compliance with the performance objectives specified at §§ 63.113(b) and (c).

(n) *Ground-Water Protection.* Separate ground-water protection standards are designed to protect the ground water resources in the vicinity of Yucca Mountain. These standards, specified at § 63.331, require the estimation of ground water concentrations in a representative volume of water. Depending on the radionuclide, the estimated concentrations must either be below a specified concentration or result in an annual, drinking water dose to the whole body or any organ ^{of the reasonably maximally exposed individual, of no greater} less than 0.04 mSv (4 mrem). Although the estimation of radionuclide concentrations in the representative volume would be a separate analysis, the analysis is similar to the performance assessment required by § 63.113(b) but subject to specific requirements for evaluation of ground-water protection specified at §§ 63.331, 63.332 and 63.342 of subpart L.

PRECLOSURE PERFORMANCE OBJECTIVES

§ 63.111 Performance objectives for the geologic repository operations area through permanent closure.

(a) *Protection against radiation exposures and releases of radioactive material.*

(1) The geologic repository operations area must meet the requirements of part 20 of this chapter.

(2) During normal operations, and for Category 1 event sequences, the annual dose to any real member of the public, located beyond the boundary of the site may not exceed the preclosure standard specified at § 63.204.

(b) *Numerical guides for design objectives.*

(1) The geologic repository operations area must be designed so that taking into consideration Category 1 event sequences and until permanent closure has been completed, the aggregate radiation exposures and the aggregate radiation levels in both restricted and unrestricted areas, and the aggregate releases of radioactive materials to unrestricted areas, will be maintained within the limits specified in paragraph (a) of this section.

(2) The geologic repository operations area must be designed so that taking into consideration any single Category 2 event sequence and until permanent closure has been completed, no individual located on, or beyond, any point on the boundary of the site, will receive, as a result of the single Category 2 event sequence, the more limiting of a TEDE of 0.05 Sv (5 rem), or the sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue (other than the lens of the eye) of 0.5 Sv (50 rem). The lens dose equivalent may not exceed 0.15 Sv (15 rem), and the shallow dose equivalent to skin may not exceed 0.5 Sv (50 rem).

(c) *Preclosure safety analysis.* A preclosure safety analysis of the geologic repository operations area that meets the requirements specified at § 63.112 must be performed. This analysis must demonstrate that:

- (1) The requirements of § 63.111(a) will be met; and
- (2) The design meets the requirements of § 63.111(b).

(d) *Performance confirmation.* The geologic repository operations area must be designed so as to permit implementation of a performance confirmation program that meets the requirements of Subpart F.

(e) *Retrievability of waste.*

(1) The geologic repository operations area must be designed to preserve the option of waste retrieval throughout the period during which wastes are being emplaced and thereafter,

(d) Consider only events that have at least one chance in 10,000 of occurring over 10,000 years.

(e) Provide the technical basis for either inclusion or exclusion of specific features, events, and processes in the performance assessment. Specific features, events, and processes must be evaluated in detail if the magnitude and time of the resulting radiological exposures to the reasonably maximally exposed individual, or radionuclide releases to the accessible environment, would be significantly changed by their omission.

(f) Provide the technical basis for either inclusion or exclusion of degradation, deterioration, or alteration processes of engineered barriers in the performance assessment, including those processes that would adversely affect the performance of natural barriers. Degradation, deterioration, or alteration processes of engineered barriers must be evaluated in detail if the magnitude and time of the resulting radiological exposures to the reasonably maximally exposed individual, or radionuclide releases to the accessible environment, would be significantly changed by their omission.

X

(g) Provide the technical basis for models used in the performance assessment such as comparisons made with outputs of detailed process-level models and/or empirical observations (e.g., laboratory testing, field investigations, and natural analogs).

§ 63.115 Requirements for multiple barriers.

Demonstration of compliance with § 63.113(a) must:

(a) Identify those design features of the engineered barrier system, and natural features of the geologic setting, that are considered barriers important to waste isolation.

(b) Describe the capability of barriers, identified as important to waste isolation, to isolate waste, taking into account uncertainties in characterizing and modeling the barriers.

(c) Provide the technical basis for the description of the capability of barriers, identified as important to waste isolation, to isolate waste. The technical basis for each barrier's capability shall be based on and consistent with the technical basis for the performance assessments used to demonstrate compliance with §§ 63.113(b) and (c).

LAND OWNERSHIP AND CONTROL

§ 63.121 Requirements for ownership and control of interests in land.

(a) Ownership of land.

(1) The geologic repository operations area must be located in and on lands that are either acquired lands under the jurisdiction and control of DOE, or lands permanently withdrawn and reserved for its use.

(2) These lands must be held free and clear of all encumbrances, if significant, such as:

(i) Rights arising under the general mining laws;

(ii) Easements for right-of-way; and

(iii) All other rights arising under lease, rights of entry, deed, patent, mortgage, appropriation, prescription, or otherwise.

(b) Additional controls for permanent closure. Appropriate controls must be established outside of the geologic repository operations area. DOE shall exercise any jurisdiction and control over surface and subsurface estates necessary to prevent adverse human actions that could significantly reduce the geologic repository's ability to achieve isolation. The rights of DOE may take the form of appropriate possessory interests, servitudes, or withdrawals from location or patent under the general mining laws.

§ 63.204 Preclosure standard.

DOE must ensure that no member of the public in the general environment receives more than an annual committed effective dose equivalent of 0.15 mSv (15 mrem) from the combination of:

- (a) management and storage (as defined in 40 CFR 191.02) of radioactive material that
 - (1) is subject to 40 CFR 191.03(a); and
 - (2) occurs outside of the Yucca Mountain repository but within the Yucca Mountain site.
- (b) storage (as defined in § 63.202) of radioactive material inside the Yucca Mountain repository.

Subpart L – Postclosure Public Health and Environmental Standards

§ 63.301 Purpose and scope.

This subpart covers the disposal of radioactive material in the Yucca Mountain repository by DOE. For the purposes of demonstrating compliance with this subpart, to the extent that there may be any conflict with the requirements specified in this subpart and the requirements contained in subparts A-J of this regulation, including definitions, the requirements in this subpart shall take precedence.

§ 63.302 Definitions for subpart L.

All definitions in subpart K of this part and the following:

Accessible environment means any point outside of the controlled area, including:

(1) the atmosphere (including the atmosphere above the surface area of the controlled area);

(2) land surfaces;

(3) surface waters;

(4) oceans; and

(5) the lithosphere.

Aquifer means a water-bearing underground geological formation, group of formations, or part of a formation (excluding perched water bodies) that can yield a significant amount of ground water to a well or spring.

Barrier means any material, structure, or feature that, for a period to be determined by NRC, prevents or substantially reduces the rate of movement of water or radionuclides from the Yucca Mountain repository to the accessible environment, or prevents the release or substantially reduces the release rate of radionuclides from the waste. For example, a barrier may be a geologic feature, an engineered structure, a canister, a waste form with physical and chemical characteristics that significantly decrease the mobility of radionuclides, or a material placed over and around the waste, provided that the material substantially delays movement of water or radionuclides.

Controlled area means:

(1) the surface area, identified by passive institutional controls, that encompasses no more than 300 square kilometers. It must not extend farther:

(a) south than 36° 40' 13.6661" north latitude, in the predominant direction of ground-water flow; and

(b) than five kilometers from the repository footprint in any other direction; and

(2) the subsurface underlying the surface area.

AFFIRMATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MERRIFIELD

SUBJECT: **SECY-01-0127 - DRAFT FINAL RULE - 10 CFR PART 63,
"DISPOSAL OF HIGH-LEVEL RADIOACTIVE WASTES IN A
PROPOSED GEOLOGIC REPOSITORY AT YUCCA
MOUNTAIN, NEVADA**

Approved XX Disapproved _____ Abstain _____

Not Participating _____

COMMENTS:

Approve subject to attached comments.



SIGNATURE

8/16/01

DATE

Entered on "STARS" Yes _____ No _____

Commissioner Merrifield's Comments on SECY-01-0127

I approve, with modifying comments provided in subsequent paragraphs, the staff's recommendation's contained in SECY-01-0127 for the publication of the final rule for 10 CFR Part 63. I would first like to first commend the staff on their significant efforts in developing this rulemaking package. Under a decidedly stressful situation, the staff produced a timely and high quality final rulemaking package for Commission consideration.

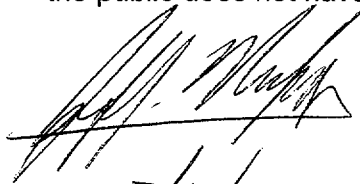
This final rule contains some key differences from the draft proposed rule the Commission issued for public comment on February 22, 1999 (64 FR 8640). Some of these changes resulted from extensive interactions with and comments received from stakeholders. The remainder of the changes resulted from NRC's incorporation of the Environmental Protection Agency's (EPA's) final environmental standards for Yucca Mountain. Although I believe that some of the requirements in the EPA standards are unnecessary and restrictive and not based in the latest scientific information (for example the separate 4 mrem/yr ground-water protection requirement), the NRC is required by law to be consistent with these standards and the staff has done a good job incorporating these standards into the rest of our regulation.

The modifications I am approving to the staff recommendations in SECY-01-0127 are as follows:

1. The final 10 CFR Part 63 rule should use total effective dose equivalent (TEDE) instead of annual effective dose equivalent (annual CEDE) for radiological doses to members of the public. Although under certain circumstances there may be some calculational differences between TEDE and annual CEDE, in the actual implementation of these concepts at Yucca Mountain the calculations of either term should produce essentially the same results. The NRC already uses TEDE in 10 CFR Part 20 of its regulations. I agree with the Chairman that it is inappropriate to use different terms for essentially the same calculations in different parts of our regulations. To use different terms for essentially the same concept in separate regulations could eventually result in inconsistent application of our regulations. I believe it is more appropriate to define the TEDE concept in 10 CFR Part 20 and its implementation methodology in supporting regulatory guidance documents. The current implementing guidance for TEDE uses Federal Guidance Report No. 11 (FGR 11) and may appropriately evolve as methods for calculating doses become more refined with future advances in science. As science advances, the NRC should maintain the flexibility to modify our regulations and methodologies as appropriate.
2. Another issue which has arisen during the review of this paper is the definition of the term "unlikely" and the probability of occurrence of an event that is considered an "unlikely event". I agree with the Chairman's vote in that the staff should initiate a separate rulemaking activity to more clearly define the term unlikely. Qualitative terms such as "unlikely" and "highly unlikely" are commonly used when performing risk analyses and are used when quantitative information is not available or when a more general perspective is used. Assigning a specific quantitative probabilistic number to qualitative words is difficult because the probability of occurrence of a specific "unlikely

event" can vary depending on the situation and the assumptions used in the analyses. Therefore during the separate rulemaking to define the term "unlikely" the staff should evaluate the pros and cons of both a range of values as well as a specific value to define "unlikely".

3. I support the Chairman's vote concerning the revisions to the definition of high-level radioactive waste in 10 CFR Part 63. The Chairman raises valid concerns about the definition as currently contained in Part 63.
4. I agree with the Chairman's concern that section 63.16(d) as currently written can be interpreted to mean that the public will be given the opportunity to comment on NRC comments prior to sending the comments to DOE. Personally, I believe the intent of the staff is that all comments which are sent to DOE will be placed in a public forum to allow the public to comment on them after the NRC comments are sent to DOE. The rule language should be modified to eliminate any ambiguity of when the staff intends to allow for public comment. Although I am fully supportive of actively soliciting public input in our regulatory process, I am not supportive of committing to provide our draft comments to the public for review prior to sending them to DOE officially. The Chairman makes a reasonable case in his vote concerning NRC comments on DOE's Site Sufficiency Review. The staff should provide their comments to DOE in a public manner and both DOE and the general public should then have the opportunity to provide a response to the NRC comments, if appropriate, but the rule should be clarified on this issue so that the public does not have a false impression of our intent.



8/16/01